IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

IN RE: PHILIPS RECALLED CPAP, BI-LEVEL PAP, AND VENTILATOR PRODUCTS LITIGATION	Master Docket: Misc. No. 21-
This Document Relates to: All Actions	MDL No. 3014

SPECIAL MASTER REPORT AND RECOMMENDATION ON THE MOTION OF DEFENDANT PHILIPS RS NORTH AMERICA LLC TO DISMISS PLAINTIFFS' AMENDED MASTER LONG FORM AND SHORT FORM COMPLAINTS FOR PERSONAL INJURIES AND DAMAGES

I. INTRODUCTION

Defendant Philips RS North America LLC (referred to in this Report and Recommendation as "Respironics" or "Philips") has moved to dismiss Plaintiffs' Amended Master Long Form Complaint and Master Short Form Complaint for Personal Injuries and Damages (ECF No. 834) pursuant to Fed. R. Civ. P. 12(b)(6) for failure to state a justiciable claim for the relief being claimed. (ECF No. 1346). Respironics also seeks dismissal of Plaintiffs' claims for personal injuries sounding in fraud pursuant to Fed. R. Civ. P. 9(b) for lack of requisite specificity.[1]

[1] In addition to being named as a defendant in the master complaint for personal injuries, Respironics is a defendant to a class action complaint for medical monitoring damages (ECF No. 815), as well as a "Consolidated Third Amended Class Action Complaint for Economic Losses," (ECF No. 785). Respironics has

The Hon. Joy Flowers Conti, presiding over this multi-district litigation, referred all non-discovery motions, including dispositive motions, to the undersigned Special Master pursuant to Fed. R. Civ. P. 53. The appointment order directed the Special Master to prepare Reports and Recommendations with respect to such non-discovery motions and authorized the Special Master to hold hearings on the referred motions.

Respironics's motion has been fully briefed. (*See* ECF No. 1346 (Respironics's Supporting Brief); ECF No. 1644 (Plaintiffs' Opposition Brief); and ECF No. 1827 (Respironics's Reply Brief). Oral arguments were presented in person on July 10 and 11, 2023. ECF No. 2129 (July 10, 2023 Transcript) and ECF No. 2130 (July 11, 2023 Transcript). By agreement of the parties, the issues presented in the extensive briefing were divided into six groups, the first four of which involve Respironics's motion to dismiss the Master Long Form ("Master Complaint" or "PIAC") and Short Form Complaints for personal injuries (sometimes referred to collectively herein as the "Operative Complaint").[2] Group 1 concerns the

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moved for dismissal of the medical monitoring claim (ECF No. 1351), and that motion will be addressed in a separate Report and Recommendation. The parties have reached a settlement of the complaint for economic losses and are presently seeking preliminary approval of that settlement. (ECF No. 2212.)

[2] One of the other two groups concerns the Master Complaint for Medical Monitoring (ECF No. 815), which is the subject of separate motion to dismiss filed on behalf of Respironics (ECF No. 1351) and which will be addressed in a separate Report and Recommendation. The final grouping of issues concerns issues raised by Defendants Polymer Technologies Inc. and Polymer Molded Products, LLC

sufficiency of the Amended Master Long Form Complaint and Master Short Form Complaints, taken together. Group 2 addresses preemption, primary jurisdiction, subsumption, and claims for negligent recall/failure to recall, and negligence *per se*. Group 3 encompasses the "learned intermediary doctrine," claims sounding in fraud, claims arising under state consumer protection statutes, and unjust enrichment claims. Group 4 covers express and implied warranty claims, negligent manufacturing, strict liability claims, battery claims, and punitive damage claims.[3] Each of the four groups will be addressed seriatim.

II. DISCUSSION

A. GROUP 1 – SUFFICIENCY OF THE PLEADINGS

The Group 1 issues address the overarching question of whether the Amended Master Long Form Complaint for Personal Injuries, taken together with the Short Form Complaint, fail to present a viable claim for relief against Respironics. In evaluating a motion to dismiss, "courts accept all factual allegations as true, construe

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(ECF No. 1341), which will be addressed in a separate Report and Recommendation.

[3] Each of the first twenty Counts of the Amended Master Long Form Complaint for Personal Injuries and Damages requests punitive damages as one of several forms of relief. Count XXI is a standalone claim for punitive damages, untethered to any specific cause of action. During oral argument, Judge Conti dismissed this Count, "without prejudice to the plaintiffs' ability to assert a right to relief in the form of punitive damages." Or. Arg. J. 11 (ECF No. 2130) at 54:22-55:8. Accordingly, the separate claim for punitive damages need not be addressed in this Report and Recommendation.

the complaint in the light most favorable to the plaintiff, and determine whether, under any reasonable reading of the complaint, the plaintiff may be entitled to relief." *Fowler v. UPMC Shadyside,* 578 F.3d 203, 210 (3d Cir. 2009) (*quoting Phillips v. Cnty. of Allegheny,* 515 F.3d 224, 233 (3d Cir. 2008). Put simply, a complaint must merely "state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal,* 556 U.S. 662, 678 (2009); *Bell Atlantic Corp. v. Twombly,* 550 U.S. 544, 570 (2007).

A plaintiff is not required to allege facts sufficient to establish a prima facie case. *Connelly v. Lane Const. Corp.*, 809 F.3d 780, 788 (3d Cir. 2016). Instead, all that is required is that a plaintiff allege "enough facts to raise a reasonable expectation that discovery will reveal evidence of' the necessary element[s]" of a viable cause of action. *Id.* at 789 (*quoting Phillips v. Cnty. of Allegheny,* 515 F.3d at 234). Liability does not need to be probable, but merely something more than "sheer possibility." *Connelly*, 809 F.3d at 786 (citing *Iqbal*, 556 U.S. at 678). At this stage of this case, "it is enough for [Plaintiffs] to allege facts sufficient to raise a reasonable expectation that discovery will uncover proof of [their] claims." *Id.* at 789.

In assessing the sufficiency of the Plaintiffs' pleadings in this MDL proceeding, the factual and procedural contexts in which their claims are presented cannot be ignored. This action was initiated in the wake of a voluntary recall of breathing assistive devices manufactured and sold by Respironics that are prescribed

for the treatment of sleep apnea. Plaintiffs' 172-page Amended Master Long Form Complaint includes the following averments:

> 2. . . . Philips manufactures and sells certain lines of products that are intended to help people breathe. These include Continuous Positive Airway Pressure ("CPAP") and Bilevel Positive Airway Pressure ("BiPAP") machines, which are commonly used to treat sleep apnea, and mechanical ventilators ("ventilators"), which treat respiratory failure. The primary function of these devices is to blow air into patients' airways. CPAP and BiPAP machines are intended for use during sleep while ventilators are used continuously when needed.
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> 3. Because these machines are used during sleep, Philips designed them to include sound-dampening foam intended to reduce noise emitted from the motors in the devices. Unfortunately, Philips designed its devices to include polyester-based polyurethane ("PE-PUR") foam, which Philips knew for many years, among other things, is susceptible to hydrolysis, the chemical breakdown of a compound due to reaction with water, particularly in medical applications. This can result in degradation of the foam and off-gassing of volatile organic compounds ("VOCs").
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> 4. On June 14, 2021, Philips . . . announced a recall of approximately 11 million of its CPAP and BiPAP machines and ventilators in the United States that were manufactured with PE-PUR foam from 2008 until the date of the recall (the "Recall"). All of these recalled products (individually referred to herein as a "Recalled Device," or collectively, as the "Recalled Devices") are defective because they contain PE-PUR foam.
> . . . .
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> 6. The use of PE-PUR foam in the Recalled Devices is a defect because the foam is susceptible to breaking down into particles which may then be inhaled or ingested by the user, and may emit VOCs that can also be inhaled, resulting in "serious injury which can be life-threatening, cause permanent impairment, and/or require medical intervention to preclude permanent impairment."
> . . . .

> 8. . . . In its Recall, Philips publicly announced that the PE-PUR foam may break down into particles and be inhaled or ingested, and may emit VOCs that can be inhaled, resulting in "serious injury which can be life-threatening, cause permanent impairment, and/or require medical intervention to preclude permanent impairment" (referred to herein as the "Defect"). Philips stated that the potential risks of exposure due to such chemicals include "headache/dizziness, irritation (eyes, nose respiratory tract, skin), hypersensitivity, nausea/vomiting, toxic and carcinogenic effects." Philips' announcement to doctors advised that these hazards could result in "serious injury which can be life-threatening or cause permanent impairment."
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> 9. In addition, on July 22, 2021, the U.S. Food and Drug Administration ("FDA") confirmed the severity of the issues described in the Recall and classified the Recall as Class I or "the most serious type of recall," meaning the Recalled Devices "may cause serious injuries or death."
> . . . .
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> 24. As a proximate result of Philips' wrongful conduct, Plaintiffs have been severely harmed; and have endured pain, suffering, disability, impairment, disfigurement, cancer diagnoses and/or an increased risk of developing cancer and/or other serious illnesses, loss of enjoyment of life, aggravation or activation of preexisting conditions, scarring, and/or inconvenience; and incurred costs for a defective device, medical care and treatment, loss of wages and wage-earning capacity, death for certain patients, and other economic and non-economic damages. The losses are permanent and continuing in nature.

(ECF No. 834 at pp. 3-4, 5, 6, 11 (footnotes omitted).)

The twenty counts in the Amended Master Long Form Complaint for Personal Injuries bring claims under the laws of negligence, products liability, warranty, and consumer protection of the states and territories of the United States. The Master

Long Form Complaint was filed pursuant to Pretrial Order 28 (ECF No. 783), to which the parties assented "[i]n light of the inefficiencies of drafting unique personal injury complaints and individual answers to those complaints" for a dispute involving thousands of plaintiffs.

Pretrial Order 28 "applies only to United States citizens or residents who have asserted, or seek to assert, personal injury claims related to the use of one or more of the recalled CPAP, Bi-Level PAP, or mechanical ventilators devices at issue in this litigation (the "Recalled Devices")." Pretrial Order 28 (ECF No. 783) at 1. Pretrial Order 28 further provides that "[a]ll claims pleaded in the Amended Master Personal Injury Complaint will supersede and replace all claims for personal injury in any action pending in this MDL." *Id.* at 2. Pretrial Order 28 then provides for a "Master Short Form Complaint" as an "an abbreviated form that each Personal Injury Plaintiff will complete, indicating their individual claims, and adopting all of the factual allegations set forth in the Amended Master Personal Injury Complaint as the basis for those individual claims." *Id.* The Amended Master Complaint and the Short Form Complaint constitute the "Operative Complaint."

The Individual Personal Injury Short Form Complaints ("Short Forms") were mandated to contain, among other things, the name of the person alleging injury; the model of each Recalled Device used; the injury or injuries allegedly resulting from use of the Recalled Device; and the identity of the specific defendant or defendants

from whom relief is being sought. *Id.* at 2-3. The Short Form provides space for additional factual allegations. Master Short Form (ECF No. 834-1) at 12-13. At this time, Respironics is only mandated to respond to the Amended Master Complaint; responses to Short Forms have been deferred until the bellwether process. *Id.* at 9.

Respironics argues that Order 28 does not relieve individual plaintiffs of the obligation under the Federal Rules of Civil Procedure to allege case-specific facts needed to state plausible claims for relief. *Id.*; Supp. Br., (ECF No. 1346) at 15. Specifically, Respironics argues that the absence of the following aspects of an individual's use of the Philips' products renders the Operative Complaint deficient:

1. That the Plaintiffs' devices manifested the defect claimed;
2. That Plaintiffs were exposed to any particular quantity or concentration of emissions;
3. Facts establishing a causal connection between use of a recalled device and an alleged injury; and
4. Facts about where/when Plaintiffs purchased products. *Id.* at 18-19.

Respironics contends that the Master Complaint alleges no ***specific*** facts about any ***specific*** plaintiffs or ***specific*** injuries. *Id.* at 19. Rather, it states general allegations that Plaintiffs, by virtue of being patients using the Devices, were exposed to harmful particles and toxins. *Id.* For that reason, argues Respironics, the Master Complaint standing alone would fail the minimum requirements to invoke this Court's Article III jurisdiction. *Id.* Moreover, since the Master Complaint only alleges conjectural injuries, and because the Short Forms neither require nor invite

individual Plaintiffs to allege that using the recalled devices ***caused*** their alleged injuries, all claims are deficient and must be dismissed. *Id.* at 20-21.

Plaintiffs respond that the Court Orders governing this MDL not only called for the Master and Short Form Complaints, but also Plaintiff Fact Sheets and supporting documents.[4] *See* Opp. Br. (ECF No. 1644) at 17 (citing Pretrial Order No. 26(a) ("Order 26(a)") – ECF 871). Order 26(a) was comprehensive and stated that all personal injury filings were to be filed pursuant to the Order. *Id.*.

An individual Plaintiff must complete and submit a Fact Sheet within 45 days of the filing of any Short Form Complaint. The Plaintiff Fact Sheets provide the kind of detail that Respironics contends is missing from the Short Form Complaint.

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[4] As one commentator has explained:

> Information obtained using fact sheets can be used to group cases for motions practice or into litigation tracks, to identify cases for targeted discovery, to select bellwether cases, and to facilitate settlement negotiations. Fact sheets may also be used to screen cases in which plaintiffs lack information to support a claim against a defendant—an issue often raised by defendants in mass-tort MDL proceedings.

Margaret S. Williams et. al, *Plaintiff Fact Sheets in Multidistrict Litigation Proceedings A Guide for Transferee Judges*, MANUAL FOR MULTIDISTRICT LITIGATION MANUAL APPENDIX J (May 2023). There are no express limitations on how fact sheets may be used in an MDL – rather, they are an informal tool not prescribed by the rules of civil procedure that assist judges in assessing the claims brought by numerous plaintiffs in Multi-District Litigation. *See* Elizabeth Chamblee Burch, *Nudges and Norms in Multidistrict Litigation: A Response to Engstrom*, 129 YALE L.J. 64 (2019).

Importantly, Respironics can challenge the sufficiency of a Plaintiff's Fact Sheet and can even seek dismissal with prejudice for a deficient fact sheet. Order 26(a) (ECF No. 871) at ¶ 12. Thus, the Fact Sheets serve the purpose of providing the information Respironics contends is missing from the Master and Short Form Complaints, and Pretrial Order 26(a) establishes a process by which Respironics can seek dismissal without going through lengthy discovery.

Respironics nonetheless persists in arguing that it is the "Operative Complaint" which must contain averments of fact sufficient both to invoke the Court's constitutional authority to entertain this litigation and to present a cognizable claim. Of course, "[t]o sue in federal court, a plaintiff must have both constitutional standing and a cause of action." *United States v. Hallinan*, 75 F.4th 148, 151 (3d Cir. 2023). To have Article III standing to bring a claim before a federal court, a plaintiff must establish:

> (1) an injury in fact (i.e., a "concrete and particularized" invasion of a "legally protected interest");
> (2) causation (i.e., a "fairly traceable" connection between the alleged injury in fact and the alleged conduct of the defendant); and
> (3) redressability (i.e., it is "likely" and not "merely speculative" that the plaintiff's injury will be remedied by the relief plaintiff seeks in bringing suit).

Common Cause of Pennsylvania v. Pennsylvania, 558 F.3d 249, 258 (3d Cir. 2009) (quoting *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560–61 (1992)).

The Operative Complaint establishes Article III standing as well as viable causes of action. *See e.g.,* PIAC (ECF No. 834) at ¶¶ 21-23, 148-151, 152-57, 161-68, 183, 185. To satisfy the first element of standing, a plaintiff must allege an actual, concrete injury in fact and cannot speculate that a future injury may occur. *See Lujan*, 504 U.S. at 556. The Master Complaint and Short Form Complaint do allege injury, *i.e.,* the exposure to toxic and harmful substances from the hydrolysis of the PE-PUR foam in the Recalled Devices. In the medical device context, the "imposition of liability, under any theory of recovery, depends upon a showing that the defendant manufactured, sold, supplied, or was in some way responsible for the product that is alleged to have caused the plaintiff's injuries." *In re Yasmin and Yaz (Drospirenone) Mktg., Sales Pracs. & Relevant Prod. Liab. Litig.,* No. 3:09-CV-20003, 2010 WL 3937414, at *5-7 (S.D. Ill. Oct. 4, 2010); *See also Sindell v. Abbott Laboratories,* 607 P.2d 924, 928 (Cal. 1980). The Operative Complaint explains that Respironics manufactured the Devices, the sound abatement foam in the Devices was subject to degradation, the PE-PUR foam released toxic particles that cause injury and illness, and the Plaintiffs inhaled those particles and suffered injuries. Those allegations are sufficient to support a reasonable inference of injury and causation at this stage to allow the claims to go forward. *See Bonner v. ISP Technologies, Inc.,* 259 F.3d 924, 928 (8th Cir. 2001) (ruling on an appeal of a jury verdict that the plaintiff did not need to produce a mathematically precise table

equating exposure levels with harm to show plaintiffs were exposed to toxic levels of a chemical).

Even if Plaintiffs had not pled ultimate illness in the Short Forms because their exposure to the toxic particles had not yet manifested as a medical condition, Plaintiffs still have pled enough at this stage. "It is well settled that exposure to toxic substances is sufficient for purposes of Article III standing." *In re Valsartan, Losartan, & Irbesartan Prod. Liab. Litig.,* No. MDL 2875 (RBK/JS), 2021 WL 100204, at *12 (D.N.J. Jan. 12, 2021). As observed in the context of a personal injury class action, *Carlough v. Amchem Prod., Inc.*, 834 F. Supp. 1437, 1454 (E.D. Pa. 1993), "exposure to a toxic substance constitutes sufficient injury in fact to give a plaintiff standing to sue in federal court." The Third Circuit has noted that in defective medical device cases, "exposure to a toxic substance causes injury; cells are damaged, and a disease mechanism has been introduced." *Reilly v. Ceridian Corp*., 664 F.3d 38, 45 (3d Cir. 2011). In this case, the Master and Short Form Complaints allege exposure to harmful substances in Respironics's devices sufficient to support a reasonable inference of injury and causation.

As noted above, Plaintiffs must plead "enough facts to raise a reasonable expectation that discovery will reveal evidence of the necessary elements." *Connelly*, 809 F.3d at 789. In this case, Pretrial Order 26 makes the Plaintiffs Fact Sheets relevant to the question of whether an individual Plaintiff has presented a

viable cause of action. Pretrial Order 26 mandates that each individual Plaintiff submit a Plaintiff Fact Sheet ("PFS") within 45 days of the submission of his or her Short Forms. Respironics has conceded that the fact sheets include elements that it contends are absent from the Complaint, such as "specifics about alleged exposure and about the medical history." Or. Arg. J. 10. (ECF No. 2129) at 11:23-25. Plaintiffs must also include specific information about device usage, prescription information, device cleaning, device storage, visible toxic particles, personal information, insurance information, and injury particulars, among other things. Order 26 (ECF No. 766), Ex. 1 at 3-15. Thus, as a practical matter, the issue is whether there could ***not*** be a reasonable expectation, based on the pleadings, that discovery will reveal evidence of the necessary elements where discovery in the form of the Plaintiff Fact Sheets has already revealed such evidence.

Here, reality must trump theory and be the preeminent consideration in whether there is a reasonable expectation, based on the pleadings, that discovery will reveal evidence of the necessary elements of a viable claim for relief. The Fact Sheets are, in effect, a hybrid pleading. They must be filed if an individual wants to proceed with a personal injury action, and their sufficiency is subject to a summary challenge by Respironics. The information which Respironics alleges is absent from the pleadings is apparent in the already-existing fact sheets. Respironics is, in fact,

in possession of the information purportedly missing from the Operative Complaint. *See* Or. Arg. J. 10 (ECF No. 2129) at 11:23-25.

Even if the Plaintiff Fact Sheets did not exist, the pleadings standard, as enunciated in *Connelly*, has been met for claims arising under the law of those States where individual Plaintiffs reside. Drawing all reasonable inferences in favor of Plaintiffs as a group, the Operative Complaint establishes exposure to harmful substances, injury in various forms, and a causal connection between the alleged injuries and the Recalled Devices. Accordingly, it will be recommended that the Court reject Respironics's challenge to the sufficiency of the Operative Complaint.

III. GROUP TWO ISSUES

The issues placed in Group Two pertain to (1) preemption, (2) primary jurisdiction; and (3) subsumption, as well as cause of action specific issues pertaining to negligent recall, negligent failure to recall, and negligence per se. Each will be addressed in turn.

A. PREEMPTION

Respironics contends that Plaintiffs' state law claims grounded on negligence, warranty, fraud, consumer protection, and unjust enrichment principles are impliedly preempted by federal law.[5] Supp. Br. (ECF No. 1346) at 25. The premise for this

[5] "The law relating to the field of medical devices presents a unique set of preemption issues." *In re Allergan Biocell Textured Breast Implant Products Liab.*

argument is that each of these claims arises out of "alleged fraud-on-the-FDA and purported non-compliance with the FDCA and its implementing regulations." *Id.* As support for its premise, Respironics points to allegations in the PIAC that concern purported violations of the Medical Device Amendments ("MDA") and implementing regulations. In particular, Respironics references allegations concerning a medical device manufacturer's duty under the MDA to adhere to "Current Good Manufacturing Practices" ("CGMP") and to investigate and report adverse events to the FDA. PIAC (ECF No. 834) at ¶ 122; *see also* PIAC at ¶¶ 123, 125-27, 129-31 (citing and referencing federal regulations and statutes giving rise to duties and responsibilities).

Litig., 537 F. Supp. 3d 679, 706 (D.N.J. 2021). The preemption provision of the Medical Device Amendments was explained in *Allergan*:

> The MDA "contains a broad express preemption provision," which: [P]roclaims 'no State ... may establish or continue in effect with respect to a device ... any requirement' that 'is different from, or in addition to,' any federal requirement and that relates either 'to the safety or effectiveness of the device' or 'to any other matter' included in a federal requirement applicable to the device. That is to say, "[s]tate requirements are pre-empted under the MDA only to the extent that they are 'different from, or in addition to' the requirements imposed by federal law." Therefore, "§ *360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements.*" [Citations omitted; emphasis added.]

Plaintiffs' allegations are, in many instances, specific to Respironics's obligations to the FDA under federal law. (*E.g.,* "Philips failed to apprise the FDA of the facts and problems it learned from its foam suppliers about premature foam degradation risks" PIAC (ECF No. 834) at ¶ 226; "Philips failed to apprise the FDA of consumer, medical provider and durable medical equipment company reports of the presence of foam particles and other device failures." *Id.* at ¶ 227. The PIAC also contains averments that the FDA has found that the Recalled Devices failed to comply with CGMP. *Id.* at ¶ 125.

While the citation to FDA reports and investigations indicates that Plaintiffs' information was derived from FDA related sources, Plaintiffs' claims do not rest on violations of federal law. Despite the reference to FDA reports, investigations, and sources, the substance of the allegations concern Respironics's actions, lack of action, and knowledge. *See id.* at ¶¶ 11, 175-81, 193, 199-205, 220-22, and 254-56. The controlling issue here is whether the fact that Plaintiffs rely upon FDA findings and purported violations of the MDA compels a determination that their state law claims are preempted.

In *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996), the Supreme Court held the Medical Device Amendments do *not* preempt state common law negligence claims against manufacturers of defective medical devices, explaining that a preemption determination cannot be made "in a 'contextual vacuum,'" *id.* at 485,

"but must be informed by two additional considerations: (1) the presumption against preemption unless clearly and manifestly indicated by Congress; and (2) the principle that 'the purpose of Congress is the ultimate touchstone' in determining the extent of preemption." *In re Orthopedic Bone Screw Products Liab. Litig.*, 193 F.3d 781, 791 (3d Cir. 1999).

The context here also includes Supreme Court pronouncements on the scope of preemption under the MDA. In *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 321 (2008), the Court held that "[t]he MDA expressly pre-empts state requirements 'different from, or in addition to, any requirement applicable ... to the device' under federal law." And in *Buckman Co. v. Plaintiffs' Legal Committee,* 531 U.S. 341, 349 n.4 (2001), the Court ruled that that "it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the [MDA]." "Thus, a private litigant cannot sue a defendant for violating the FDCA. Similarly, a private litigant cannot bring a state-law claim against a defendant when the state-law claim is in substance (even if not in form) a claim for violating the FDCA—that is, when the state claim would not exist if the FDCA did not exist." *Riley v. Cordis Corp*., 625 F. Supp. 2d 769, 776–77 (D. Minn. 2009).

"[T]he Medical Device Amendments of 1976 . . . 'swept back some state obligations and imposed a regime of detailed federal oversight.'" *Shuker v. Smith & Nephew*, PLC, 885 F.3d 760, 765 (3d Cir. 2018), *quoting* Riegel, 552 U.S. at 315-

16. "Congress's approach . . . was twofold: first, it established a system of federal regulation over the introduction of new devices, instituting tiered federal requirements calibrated to each device's risk level, and, second, it enacted a provision stating that federal medical device requirements supersede any *different or additional* state safety or effectiveness requirements." *Shuker*, 885 F.3d at 765 (emphasis added). As the Third Circuit in *Shuker* explained:

> The [MDA] . . . preempts any state requirement that has 'the effect of establishing a substantive requirement for [the] specific device' in question that relates to safety, effectiveness, or 'any other matter' that forms a federal requirement, so long as the state requirement is 'different from, or in addition to,' the federal mandate. The 'overarching concern' behind this provision is 'that pre-emption occur only where a particular state requirement threatens to interfere with a specific federal interest.'

State law concerning the safety of medical devices, however, is "not shut out entirely." *Id.* at 767. "[C]laims premised on state requirements that merely incorporate applicable federal requirements and therefore are not 'different from, or in addition to,' federal requirements," *id.,* are not preempted. Such state law claims are regarded as "parallel" to the MDA substantive obligations. *See also Freed v. St. Jude Med., Inc.,* 364 F. Supp. 3d 343, 350–51 (D. Del. 2019) ("The MDA's express preemption provision does not apply to 'parallel' claims—that is, to claims premised on state requirements that merely incorporate federal requirements and therefore are not 'different from, or in addition to,' federal requirements."); *Bull v. St. Jude Med.,*

Inc., No. 17-1141, 2018 WL 3397544 at *9, (E.D. Pa. July 12, 2018) ("State law claims that allege liability based on a common law tort theory and which parallel federal law claims ... are not impliedly preempted. . . .").

Respironics characterizes Plaintiffs' allegations as an attempt to privately enforce the Food Drug & Cosmetic Act ("FDCA"). Supp. Br. (ECF No. 1346) at 25; 21 U.S.C. § 337(a). In making its assertions, Respironics relies on *Buckman,* which held that a state "fraud-on-the-FDA" claim was preempted because it conflicted with federal law, and because the plaintiffs in that case were not relying on state law, but solely on obligations imposed by the FDCA. *Id.* at 353.

There is no private right of action under the FDCA. 21 U.S.C. § 337(a); *Gile v. Optical Radiation Corp.*, 22 F.3d 540, 544 (3d Cir. 1994); *Buckman*, 531 U.S. at 353; *Parker v. Stryker Corp.*, 584 F.Supp.2d 1298, 1301 (D. Colo. 2008). However, there is no indication, such as a separate count, that Plaintiffs' intention is to enforce the FDCA.

To avoid preemption, a claim must arise out of state law duties, not solely out of violations of the FDCA. *Bausch*, 630 F.3d at 557-58. As an example of something that does not fit into the narrow gap, the Court in *Buckman* ruled in favor of preemption because the claims in that case existed "*solely* by virtue of the FDCA disclosure requirements" and did not arise from state-law duties. *Buckman*, 531 U.S. at 352-53 (emphasis added). Preemption under *Buckman* often does not extend

beyond "fraud-on-the-agency" claims. *See id; Allergan*, 537 F.Supp.3d at 711; *Bausch v. Stryker Corp.*, 630 F.3d 546, 557-58 (7th Cir. 2010); *Bull v. St. Jude Med., Inc.*, No. 17-1141, 2018 WL 3397544, at *9 (E.D. Pa. July 12, 2018).

To determine whether state law claims implicating the MDA are preempted, the Third Circuit utilizes a two-part framework. *Shuker*, 885 F.3d at 771. The Third Circuit asks 1) has the federal government established requirements applicable to the device at issue, and 2) if yes, whether the plaintiff's claims are based on state requirements that are "different from, or in addition to" the federal requirements, and whether they relate to safety and effectiveness. *Shuker*, 885 F.3d at 771. If both answers are yes, there is preemption. *See Ramirez*, 961 F.Supp.2d at 977.

Application of this two-part test to the claims as alleged in the PIAC results in a determination that the claims are not preempted. Plaintiffs' fraud claim merely describes Respironics alleged behavior. PIAC (ECF No. 834) at ¶¶ 563-80.) In *Buckman*, the plaintiffs claimed that "petitioner made fraudulent representations to the Food and Drug Administration (FDA or Administration) in the course of obtaining approval to market the screws" and that "such representations were at least a "but for" cause of injuries that plaintiffs sustained from the implantation of these devices: Had the representations not been made, the FDA would not have approved the devices, and plaintiffs would not have been injured." *Buckman*, 531 U.S. at 343. Unlike in *Buckman*, it is not clear that Plaintiffs' claims are a mere

proxy for fraud-on-the-FDA claims. Merely mentioning federal law throughout the PIAC is not tantamount to basing claims on federal law. There is also nothing to indicate that any part of the state fraud claims is "different from, or in addition to" the federal requirements.

Similarly, Plaintiffs' negligence claims do not rely on alleged violations of the FDCA. When negligence claims arise out of violations of the FDCA, they are preempted. *See Williams v. Zimmer US Inc.*, No. 5:14-CV-468-F, 2015 WL 4256249, at *7 (E.D.N.C. July 14, 2015) (holding that negligence claims alleging violations of FDA regulations and violations of the FDCA were preempted because the claims were based on violations of those federal regulations); *Franklin v. Medtronic, Inc.*, No. 09-cv-02301-REB-KMT, 2010 WL 2543579, at *8 (D. Colo. May 12, 2010) (holding that negligence per se claims alleging FDCA violations were preempted because the claims arose out of the FDCA and failed to assert "parallel" claims). However, mere mention of federal law does not amount to claims based on federal law. There is also nothing to indicate that any part of the state negligence claims is "different from, or in addition to" the federal requirements.

Finally, Plaintiffs' negligent recall claim is not preempted because it does not rely on Section 518(a) of the FDCA, which regulates recall notifications for medical devices. If Plaintiffs' claim relies on any part of the FDCA, which includes § 518(a), the claim would conflict with the FDCA's enforcement scheme and be preempted.

Perez v. Nidek Co., 711 F.3d 1109, 1119 (9th Cir. 2013). The PIAC references Section 518(a) to support Plaintiffs' position that Respironics's recall was negligent. PIAC (ECF No. 834) at ¶ 130. The PIAC does not, however, expressly refer to Section 518(a) as the standard of care. *Id.* at ¶131. The PIAC states that, "In issuing a voluntary recall, Philips assumed duties to exercise reasonable care in issuing and implementing the recall." *Id.* This language suggests that, although this claim references Section 518(a), it does not rely on it. There is also nothing to suggest the state law duties are "different from, or in addition to" the federal requirements. *See Shuker*, 885 F.3d at 771.

Plaintiffs' negligence-based claims refer to Respironics's actions that allegedly violated statutes and regulations "including but not limited to 21 C.F.R. § 807 *et. seq.*, and parallel state law requirements." PIAC (ECF No. 834) at ¶¶ 597-98.[6] The breach of implied warranty claim cites both federal and state law. *Id.* at ¶¶ 513-15 (stating that the states codified federal statutes or regulations). The fraud

[6] Plaintiffs allege:

> 597. Philips' actions as described herein violated applicable statutes and regulations related to, at a minimum, the 510(k) application process, including but not limited to 21 C.F.R. § 807 et seq., and parallel state law requirements.
> 598. Philips' actions as described herein violated applicable statutes and regulations related to its duty to monitor, investigate, evaluate and timely report issues with foam degradation, including 21 C.F.R. part 803 and 21 C.F.R. § 820.198, and parallel state law requirements.

and unjust enrichment claims do not reference state or federal law – they merely describe Respironics's alleged wrongful behavior. *Id.* at ¶¶ 563-580, 625-41. Specific state consumer protection laws are listed for the purpose of stating the consumer protection claims. *Id.* at ¶ 617.

In summary, Plaintiffs' state law claims, as alleged in the PIAC, are parallel, and not in addition to the alleged violations of the MDA. Accordingly, it is recommended that the motion to dismiss on the basis of preemption be denied.

B. PRIMARY JURISDICTION

Respironics argues that, separate from preemption, the negligent recall claim should be dismissed under the primary jurisdiction doctrine because the FDA has the enforcement mechanisms most appropriate to handle the instant matter. Supp. Br. (ECF No. 1346) at 29. The doctrine of primary jurisdiction comes into play whenever enforcement of a claim otherwise cognizable in a court "requires the resolution of issues which, under a regulatory scheme, have been placed within the special competence of an administrative body; in such a case the judicial process is suspended pending referral of such issues to the administrative body for its views." *Raritan Baykeeper v. NL Industries, Inc.*, 660 F.3d 686, 691 (3d Cir. 2011).

Four factors are assessed to determine whether the court should defer to an administrative agency: 1) the issue involves technical or policy considerations within an agency's expertise as opposed to being in the conventional experience of judges;

2) the issue is within the agency's discretion; 3) there is a danger of inconsistent rulings; and 4) a prior application to the agency has been made. *Id.*

In response to Respironics's argument that the negligent recall claim should be dismissed under the primary jurisdiction doctrine, Plaintiffs assert that the primary jurisdiction doctrine only applies in exceptional cases where the relevant technical and policy questions should be left to a regulatory authority. Opp. Br. (ECF No. 1644) at 17-18. Plaintiffs assert that primary jurisdiction does not apply to this case because Congress has made it explicit that an FDA recall does not relieve a manufacturer from claims under federal and state law and Courts "generally do not defer jurisdiction." *Id.* at 18. Plaintiffs also challenge Respironics's assessment of the four *Baykeeper* factors for evaluating primary jurisdiction. *Id.* The main issue here is whether Respironics complied with its duties to adequately notify and promptly replace the Devices, an issue well within the Court's normal range of competence. *Id.* Regarding the third and fourth factors, Plaintiffs contend that there is no risk of inconsistent rulings because they do not seek a remedy that conflicts with the FDCA or actions taken by the FDA. *Id.*

Under certain circumstances, courts must defer to administrative agencies like the FDA. *In re Human Tissue Prods. Liab. Litig.*, 488 F.Supp.2d 430, 432 (D.N.J. 2007) (holding with regard to a motion to require notice that federal regulations give the FDA the authority to set specific procedures by which recall communications

should be provided and that "[i]mplicit in this authority is the understanding that the FDA possesses the necessary expertise to determine when notice is required, what the notice should contain, and who the notice should be sent to"). However, the text of the FDCA itself indicates that this is not an "exceptional case" where the court should abstain from exercising its jurisdiction – Congress has opened the door to judicial oversight of the recalls of medical devices. 21 U.S.C. §360h(d) (stating within the section of the FDCA relating to notification and other remedies available when a device intended for human use is distributed in interstate commerce presents an unreasonable risk of substantial harm that "[c]ompliance with an order issued under this section shall not relieve any person from liability under Federal or State law"); *See also Baykeeper v. NL Indus., Inc.*, 660 F.3d 686, 691 (3d Cir. 2011).

Baykeeper lays out four factors the Third Circuit may use to determine whether a court should abstain under primary jurisdiction. *Baykeeper*, 660 F.3d at 691; *Global Naps, Inc. v. Bell Atl.-N.J., Inc.*, 287 F.Supp.2d 532, 549 (D.N.J. 2003). Those factors are:

1) Whether the question at issue is within the conventional experience of judges or whether it involves technical or policy considerations within the agency's particular field of expertise;
2) Whether the question at issue is particularly within the agency's discretion;
3) Whether there exists a substantial danger of inconsistent rulings; and
4) Whether a prior application to the agency has been made.

Factor one weighs in favor of Plaintiffs. The FDA has already determined that a recall of the Devices is warranted. It has also determined that the Recalled Devices are "adulterated," *i.e.*, do not comply with CGMP. Whether Respironics failed to act with reasonable care in undertaking the recall is the type of issue that falls squarely with the conventional experience of judges.

With regard to factor two, Respironics is correct that regulation of CPAP machines falls within the scope of the FDA and that the FDA has expertise in the subject matter. *In re Human Tissue Prods. Liab. Litig.*, 488 F. Supp. 2d 430, 431-33 (D.N.J. 2007) (finding that the matter at issue was within the authority of the FDA because the FDCA and its regulations give the FDA the authority to regulate product recall partially because the FDA had special expertise on the subject matter). However, the key issues in the negligent recall claim are whether Respironics had a duty and whether Respironics violated that duty – issues well within the domain of the court. In *In re Valsartan*, the court considered the *Baykeeper* factors and reasoned that reviewing scientific and technical literature was within its purview. *In re Valsartan, Losartan, and Irbesartan Prods. Liab. Litig.*, 2020 WL 7418006, at *12 (D.N.J. Dec. 18, 2020) (holding that expert reports will inform the court as to any scientific and technical matters relating to implied warranty, strict liability-failure to warn, negligence, and manufacturing defect and because the FDA already

decided the issue, the experts would help inform the court on the FDA's decisions). Thus, the second factor weighs in favor of Plaintiffs.

The third factor also weighs in favor of Plaintiffs – Plaintiff's negligent recall claim is not based on FDA recall requirements. Contrary to *Harshbarger v. Pa. Mut. Life Ins. Co.*, No. 12-6172, 2014 WL 1409445, at *6 (E.D. Pa. Apr. 11, 2014), where the court reasoned that there was a significant danger of inconsistent rulings because the court would have had to interpret the same state statutes and regulations as the Pennsylvania Insurance Department, the court will not need to analyze FDA regulations. Similarly, here, though the FDA has continuing oversight of the recall, the FDA has expressed that the recall has occurred too slowly. *See* Or. Arg. J. 10 (ECF No. 2129) at 60:25-61:11. Moreover, the relevant federal statute leaves open the possibility of liability under state law:

> Compliance with an order issued under this section shall not relieve any person from liability under Federal or State law. In awarding damages for economic loss in an action brought for the enforcement of any such liability, the value to the plaintiff in such action of any remedy provided him under such order shall be taken into account." 21 U.S.C.A. § 360h(d).

The fourth factor weighs in favor of Respironics because an application to the agency has been made – the FDA is conducting an active investigation. *See Cohen v. Subaru of Am., Inc.*, No. 120CV08442JHRAMD, 2022 WL 721307, at *40; *See also* Or. Arg. J. 10 (ECF No. 2129) at 60:21-22. However, an application to an agency is not dispositive, nor is it weighed heavily. *See id.* at *37 (briefly discussing

the fourth factor and stating that even though a car manufacturer initiated a recall with the regulatory agency, that factor alone does not justify abstention by the court).

Weighing the *Baykeeper* factors here compels the conclusion that abstention under the primary jurisdiction is not warranted. This determination gives recognition to the fact that "Federal courts have a 'virtually unflagging obligation ... to exercise the jurisdiction given them.'" *Colo. River Water Conservation Dist. v. United States*, 424 U.S. 800, 817 (1976). "Abstention, therefore, is the exception rather than the rule." *Riley v. Simmons*, 45 F.3d 764, 771 (3d Cir. 1995). Accordingly, it will be recommended that the motion to dismiss the negligent recall claim on the basis of primary jurisdiction be denied.

C. SUBSUMPTION

The PIAC asserts generic causes of action for personal injury damages sounding in negligence, strict liability, breach of express warranty, implied warranty, battery, loss of consortium, wrongful death, medical monitoring, punitive damages, common law fraud, and violations of state consumer protection acts. That is, the PIAC does not assert claims under the law of any particular state or territory. Respironics, however, has moved for dismissal of some particular claims on the basis of specific state products liability acts, contending that the product liability acts ("PLAs") of nine states create an exclusive statutory cause of action for claims falling within their purview – actions asserting physical harm resulting from an

allegedly defective product.[7] Respironics thus argues that Plaintiffs' claims should be dismissed under those respective state laws because those PLAs subsume common law and state consumer protection law causes of action. *Id.* at 19. They further argue that amendment is not the proper remedy as Plaintiffs were aware of the PLAs when they last amended their PIAC and the claims are sufficiently broad to be ruled on at this stage. Repl. Br. (ECF No. 1827) at 19.

Plaintiffs argue that while *some* of the acts cited by Respironics possibly subsume or prohibit *some* of the causes of action challenged by Respironics, Respironics overstates the impact of a subsumption ruling. Opp. Br. (ECF No. 1644) at 32. They further assert that many of the PLAs Respironics mentions merely merge claims into one and thus the proper remedy would be to allow for an amendment to the PIAC.

Contrary to Plaintiffs' assertion, it does appear that it is appropriate to consider and rule upon Respironics's state-by-state arguments at this time. In this regard, other MDL courts have made state-by-state rulings at the motion to dismiss stage. *E.g., In re Valsartan, Losartan, and Irbesartan Products Liab. Litig.,* No. MDL 2875 (RBK/KW), 2021 WL 364663 (D.N.J. Feb. 3, 2021) (deciding subsumption arguments at the motion to dismiss stage). Plaintiffs have not cited

[7] Those states include Connecticut, Indiana, Kansas, Louisiana, Mississippi, New Jersey, Ohio, Tennessee, and Washington.

dispositive authority to support their assertion that the Court should defer its consideration of this issue. Accordingly, the PLAs of the states cited by Respironics will be addressed now.

Under the Connecticut Product Liability Act ("CPLA"), common law claims in product liability actions are not abolished, but instead incorporated into a single count to simplify pleadings. *Collazo v. Nutribullet*, 473 F.Supp.3d 49, 51 (D. Conn. 2020); Conn. Gen. Stat. Ann. § 52-572m. Separate counts are precluded in that the CPLA provides the exclusive remedy for such claims, but the substance of common law claims can be asserted under the CPLA unless they are expressly inconsistent with it. *Collazo,* 473 F. Supp.3d at 51-52. Additionally, consumer protection act causes of action asserting physical harm to a person or property resulting from an allegedly defective product are subsumed by the CPLA where the plaintiff seeks a remedy for personal injury, death, or property damage. *Gerrity v. R.J. Reynolds Tobacco Co.*, 818 A.2d 769, 775 (Conn. 2003). Accordingly, it will be recommended that personal injury claims asserted under Connecticut law are subsumed by the CPLA.

The Indiana Product Liability Act ("IPLA") only allows certain claims to be pled; all other covered claims not pled under the IPLA are barred. *Palm v. Taurus Int'l Mfg., Inc.*, No. 3:22-CV-337 DRL-MGG, 2022 WL 17714600 at *4-5 (N.D. Ind. Dec. 15, 2022); *See also In re Valsartan,* 2021 WL 364663, at *13, *26 (finding,

among other things, that all of the Indiana personal injury claims at issue, "except for violation of state consumer protection statutes, breach of express warranty, and breach of implied warranty are subsumed by the Indiana Products Liability Act"). The IPLA governs "all actions that are: (1) brought by a user or consumer; (2) against a manufacturer or seller; and (3) for physical harm caused by a product; regardless of the substantive legal theory upon which the action is brought." *Elward v. Electrolux Home Products, Inc.*, 264 F. Supp. 3d 877, 895 (N.D. Ill. 2017); Ind. Code Ann. § 34-20-1-1. "In *Dague v. Piper Aircraft Corp*., 275 Ind. 520, 528, 418 N.E.2d 207, 212 (1981), [the Indiana Supreme Court] determined that it was 'clear the legislature intended that the [IPLA] govern all product liability actions, whether the theory of liability is negligence or strict liability in tort.'" *Stegemoller v. ACandS, Inc.*, 767 N.E.2d 974, 975 (Ind. 2002). Thus, it will be recommended that all tort claims and warranty claims alleging personal injury from a product defect not pled under the IPLA are subsumed. *See Palm*, 2022 WL 17714600 at *4-5. It will be recommended that Plaintiffs' consumer protection claims are not.

Under the Kansas Product Liability Act ("KPLA"), Plaintiffs can only recover under one theory of liability. *Mattos v. Eli Lilly & Co.*, No. 12-1014, 2012 WL 1893551, at*2 (D. Kan. May 23, 2012) (dismissing all claims not brought under the KPLA or KCPA including the "plaintiff's claims for negligence, negligence per se, breach of implied warranty, breach of express warranty, misrepresentation by

omission, and fraudulent misrepresentation"). Accordingly, it will be recommended that all strict liability in tort, negligence, breach of warranty, misrepresentation, fraud, and all other products liability actions are subsumed and merged into one claim. *Id.*

The Louisiana Products Liability Act ("LPLA") limits plaintiffs to four theories of recovery: construction or composition defect, design defect, inadequate warning, and breach of express warranty. *McKinney v. Superior Van & Mobility, LLC*, No. CV 20-1169, 2021 WL 1238906, *3 (E.D. La. Apr. 2, 2021); La. Stat. Ann. § 9:2800.54. The LPLA provides that those four theories of recovery are exclusive – a plaintiff suing a manufacturer based on damages caused by its product, or alleging a product liability claim, may proceed only under the LPLA. *See* La. Stat. Ann. § 9:2800.52 ("This Chapter establishes the exclusive theories of liability for manufacturers for damage caused by their products. A claimant may not recover from a manufacturer for damage caused by a product on the basis of any theory of liability that is not set forth in this Chapter.") That includes claims pursued under the applicable consumer protection act if the theory of liability is that a manufacturer caused damage through its products. *Mayard v. St. Jude Medical Inc.*, No. 6:19-CV-00761, 2019 WL 7476714 at *3 (E.D. La. Apr. 2, 2021) (stating that '[a] claimant may not recover from a manufacturer for damage caused by a product on the basis of any theory of liability that is not set forth in'" the LPLA). The only exception is

a "redhibition" claim – a claim which Plaintiffs have not made in the PIAC. *Stroderd v. Yamaha Motor Corp., U.S.A.*, No. 04-3040, 2005 WL 2037419 at *2 (E.D. La. Aug. 4, 2005). Thus, it will be recommended that all of Plaintiffs' personal injury claims asserted under Louisiana law, including the relevant consumer protection claims, are subsumed, and should be dismissed.

Under the Mississippi Products Liability Act ("MPLA"), common law causes of action that assert damages resulting from an allegedly defective product are subsumed. *Young v. Bristol-Myers Squibb Co.*, No. 416CV00108DMBJMV, 2017 WL 706320, *3 (N.D. Miss. Feb. 22, 2017); Miss. Code. Ann. § 11-1-63. Claims that are subsumed do not need to be dismissed merely because they fall under the MPLA. However, "practically, where a common law claim is subsumed by the MPLA and is brought alongside products liability claims based on the same theory . . . the proper course is to dismiss the common law claim . . . parallel [to the] products liability counts." *Id.* at *3-4 (also stating that "Common law claims for damages caused by a product which seek to impose liability outside the MPLA's framework must be dismissed for failure to state a claim"). Thus, it will be recommended that all of Plaintiffs' personal injury claims asserted under Mississippi law be dismissed as subsumed by the MPLA.

Under the New Jersey Product Liability Act ("NJPLA"), common law causes of action relating to harm caused by consumer and other products except for claims

for breach of an express warranty are subsumed. *Calender v. NVR Inc.*, 548 F. App'x 761, 764 (3d Cir. 2013); N.J. Stat. Ann. § 2A:58C-1. The NJPLA is the exclusive remedy for such actions and other claims are subsumed. *See id.* Thus, it will be recommended that Plaintiffs' claims for personal injuries under New Jersey law be limited to the NJPLA claims.

With respect to the Ohio Product Liability Act ("OPLA"), any claim alleging injury related directly to a product is covered, and the OPLA is the exclusive means of recovery for covered claims. *Mitchell v. Proctor & Gamble*, 2:09-cv-426, 2010 WL 728222, at *3 (S.D. Ohio Mar. 1, 2010). Thus, any claim for recovery of compensatory or punitive damages for a defective product, such as Plaintiffs' claims here, are subsumed by the OPLA. *Id.* Claims made under the Ohio Consumer Protection Act ("OCSPA") are likewise subsumed where only damages for personal injury are sought. *Traxler v. PPG Indus., Inc.*, 158 F.Supp.3d 607, 628 (N.D. Ohio 2016). Thus, it will be recommended that all of Plaintiffs' personal injury claims asserted under Ohio law are subsumed and should be limited to the OPLA.

The Tennessee Product Liability Act ("TPLA") covers "all actions brought for or on account of personal injury, death or property damage caused by or resulting from the manufacture, construction, design, formula, preparation, assembly, testing, service, warning, instruction, marketing, packaging or labeling of any product." Tenn. Code Ann. § 29-28-102. "All product-liability claims are subsumed by the

TPLA regardless of the substantive theory of recovery." *Cash-Darling v. Recycling Equip., Inc*., 62 F.4th 969, 975 (6th Cir. 2023). "Although the TPLA provides a statutory framework for product liability claims made under Tennessee law, plaintiffs can still bring claims under that statute based on multiple traditional common law theories of product liability." *In re Acetaminophen - ASD-ADHD Products Liab. Litig*., No. 22CV9011 (DLC), 2023 WL 3045802, at *5 (S.D.N.Y. Apr. 21, 2023). However, under Tennessee law, mere failure to cite the TPLA is not sufficient for dismissal – claims based on common law theories of liability can still be brought. *In re Acetaminophen - ASD-ADHD Prod. Liab. Litig.*, No. 22CV9011 (DLC), 2023 WL 3045802, *5-6 (S.D.N.Y. Apr. 21, 2023). "Courts applying Tennessee law have routinely held that the term 'products liability action' is cast so expansively as to cover claims related to a defective product under legal theories of many kinds, whether sounding in negligence, misrepresentation, or breach of warranty." *Strayhorn v. Wyeth Pharm., Inc*., 882 F. Supp. 2d 1020, 1028 (W.D. Tenn. 2012), *aff'd*, 737 F.3d 378 (6th Cir. 2013). Accordingly, it will be recommended that Respironics's motion to dismiss claims under Tennessee law be granted to the extent that the TPLA provides the exclusive basis for a claim for personal injury damages.

The Washington Product Liability Act ("WPLA") WPLA "is the exclusive remedy for product liability claims. It supplants all common law claims or actions

based on harm caused by a product." *Macias v. Saberhagen Holdings, Inc.*, 282 P.3d 1069, 1073–74 (Wash. 2012) (en banc). Because "[t]he WPLA is the exclusive remedy for product liability claims," *id.,* it will be recommended that claims for personal injury damages under Washington law be limited to the WPLA.

D. NEGLIGENT RECALL

Count VI of the PIAC is a claim for "Negligent Recall/Negligent Failure to Recall." Plaintiffs allege that Respironics, despite being aware of the defect in the Devices as early as 2008, did not initiate a recall until 2021. PIAC (ECF No. 834) at ¶ 414. They further allege that in 2008, and no later than 2015, Respironics knew or reasonably should have known about the defects and exposure to toxins. *Id.* at ¶ 416. Plaintiffs assert that had Respironics initiated a recall earlier, Plaintiffs would not have used the Devices. Instead, they would have sought available alternatives. *Id.* at ¶ 419.

Plaintiffs further allege that the recall was implemented negligently – notice was inadequate and the timeline for replacement units was unworkable. *Id.* at ¶¶ 421-24. Plaintiffs also allege that customers were not given adequate information about replacements or any guidance on how to proceed and many are still waiting for a replacement. *Id.* at ¶¶ 425, 428.

Respironics argues that ten states do not recognize negligent failure to recall as an independent cause of action. Plaintiffs concede that point for Indiana,

Mississippi, Missouri, and Ohio, Repl. Br. (ECF No. 1827) at 8, and it will be recommended that negligent failure to recall claims for those states be dismissed. Respironics also argues that Plaintiffs' allegations foreclose their negligent failure to recall claims because Respironics voluntarily initiated a recall, and thus did not fail to recall defective products. Supp. Br. (ECF No. 1346) at 18.

Plaintiffs contend that six of the states subject to Respironics's challenge either have caselaw that recognizes negligent failure to recall or has no caselaw deciding the issue. Opp. Br. (ECF No. 1644) at 19. A state-by-state review follows.

In Alaska, while the state's highest court has not clearly addressed the claim, lower courts have rejected a negligent failure to recall claim. *E.g., Nelson v. Original Smith & Wesson Bus. Entities &/or Corps.*, No. 4:10-CV-0003 RBB, 2010 WL 7125187, at *1 (D. Alaska June 14, 2010) (dismissing a negligence claim because "claims for failure to warn and failure to recall or retrofit also fail to allege any legal basis for a duty to warn, recall, or retrofit"). Therefore, it will be recommended that Plaintiffs' negligent failure to recall claim asserted under Alaska law be dismissed.

In Illinois, a negligent failure to recall claim is only viable where plaintiffs allege that the defendants knew about an alleged defect prior to a sale: "absent a statutory obligation or voluntary undertaking . . . no Illinois case has imposed upon a manufacturer a duty to retrofit or recall where the allegedly dangerous condition was not discovered until after the product was sold." *Smith v. BOC Grp. PLC*, 2001

WL 477237, at *5 (N.D. Ill. May 4, 2001). Here, the PIAC alleges that Respironics had knowledge of the alleged defects as early as 2008 but did not initiate a recall until 2021. PIAC (ECF No. 834) at ¶ 414. Thus, under Illinois law, a negligent failure to recall could be applicable for products sold between 2008 and 2021. Accordingly, it will be recommended that the negligent failure to recall claim under Illinois law not be dismissed.

Negligent failure to recall claims are not viable under Nebraska law. *Dubas v. Clark Equip. Co.*, 532 F. Supp. 3d 819, 829-30 (D. Neb. 2021) (finding that "such claims are not actionable under Nebraska law"). Therefore, it will be recommended that Plaintiffs' negligent failure to recall claim asserted under Nebraska law be dismissed.

Contrary to Respironics's assertion, Oklahoma recognizes a viable claim for negligence in the context of a product recall. *See In re Gen. Motors LLC Ignition Switch Litig.*, 154 F. Supp. 3d 30, 44 (S.D.N.Y. 2015) ("when the company undertook the ignition switch recall—which was 'necessary for the protection of [an]other's person or thing'—it exposed itself to liability if the recall was carried out negligently and caused injury."). Accordingly, it will be recommended that Respironics's motion to dismiss the negligent recall claim under Oklahoma law be denied.

"Under Pennsylvania law, manufacturers and distributors do not have a duty to recall or retrofit products." *Cleaver v. Honeywell Intl., LLC*, No. CV 21-4921, 2022 WL 2442804, at *4 (E.D. Pa. Mar. 31, 2022) (*citing Habecker v. Copperloy Corp.,* 893 F.2d 49, 53 (3d Cir. 1990). Accordingly, it will be recommended that Respironics's motion to dismiss the negligent recall claim under Pennsylvania law be granted. That determination, however, would not preclude a negligence claim for distribution of the Devices after Philips had knowledge of their defective conditions. *See Lance v. Wyeth*, 85 A.3d 434, 460 (Pa. 2014) ("Whatever the policy considerations may be in the recall/retrofit arena, we are convinced that a manufacturer or supplier has a duty to cease further distribution of a product at such point as it may know, or may reasonably be charged with knowledge that the commodity is too dangerous to be used by anyone.").

"Texas law generally does not recognize a common law post-sale duty to warn or to recall defective products." *Hernandez v. Ford Motor Co.*, No. C.A. C-04-319, 2005 WL 1574474, at *1 (S.D. Tex. June 28, 2005). *See also Syrie v. Knoll Int'l*, 748 F.2d 304, 311-12 (5th Cir. 1984) ("Texas does not impose on manufacturers the duty to warn about or to recall products for which a safer design has been developed"). Accordingly, it will be recommended that Respironics's motion to dismiss the negligent recall claim under Texas law be granted.

E. NEGLIGENCE PER SE AS AN INDEPENDENT CAUSE OF ACTION

Count XV of the PIAC asserts a claim for negligence per se based upon Plaintiffs' averments that Respironics "violated applicable statutes and regulations related to, at a minimum, the 510(k) application process, including but not limited to 21 C.F.R. § 807 et seq., and parallel state law requirements." PIAC (ECF No. 834) at ¶ 597. Contending that they fall within the class of persons intended to be protected by the applicable statutory and regulatory provisions *id.* at ¶ 599, Plaintiffs claim a right to recover under a negligence per se theory.

Stated succinctly, Respironics's argument is that twenty-seven states do not recognize negligence per se as a cause of action, and therefore Plaintiffs' claim should be dismissed with regard to the state law of those twenty-seven states. Supp. Br. (ECF No. 1346) at 51-52.[8] Plaintiffs respond by asserting that the cases cited by Respironics do not prohibit negligence per se, but merely integrate it into a typical negligence claim. Opp. Br. (ECF No. 1644) at 51. They argue that this is a case specific issue better left for the bellwether process. *Id.*

[8] The twenty-seven states at issue are Alabama, Arizona, Arkansas, California, Hawaii, Illinois, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, North Dakota, Nebraska, Nevada, New Mexico, Oregon, Pennsylvania, Rhode Island, Tennessee, Texas, Utah, Vermont, Virginia, Washington, and Wisconsin.

Fifteen, states, however, do not recognize an independent negligence per se claim, and thus mandate that such claims be dismissed. *See Prickett v. BAC Home Loans*, 946 F.Supp.2d 1236, 1247 (N.D. Ala. 2013) ("There is no Alabama tort cause of action known as negligence per se. Rather, negligence per se is merely a subsidiary doctrine of negligence whereby a party is considered negligent as a matter of law because it acted in violation of a statute which was designed to prevent the type of harm that occurred."); *People of California v. Kinder Morgan Energy Partners, L.P.*, 569 F.Supp.2d 1073, 1087 (S.D. Cal. 2008) (Under the "case law and the California Evidence Code, negligence *per se* is merely an evidentiary doctrine and not an independent cause of action"); *Aana v. Pioneer Hi-Bred Int'l, Inc.*, 965 F.Supp.2d 1157, 1175 (D. Haw. 2013) (finding that Hawaii law does not recognize negligence per se causes of action and, thus, "a negligence per se claim distinct from Plaintiffs' general negligence claim . . . fails as a matter of law"); *Ducote v. Boleware*, 216 So. 3d 934, 944 (La. App. 4th Cir. 2016) ("Louisiana does not recognize the negligence per se doctrine"); *Bray v. Marriott Intl.*, 158 F.Supp.3d 441, 445 (D. Md. 2016) ("[T]here is no cause of action for negligence per se under Maryland law."); *Deutsche Lufthansa AG v. Massachusetts Port Auth.*, No. 17-CV-11702-DJC, 2018 WL 3466938, *2 (D. Mass. July 18, 2018) ("The Supreme Judicial Court has repeatedly reaffirmed the principle that negligence per se does not exist as a cause of action independent from a general negligence action because violation of

the statute can only be some evidence of the defendant's negligence."); *Abnet v. Coca-Cola Co.*, 786 F.Supp.2d 1341, 1345 (W.D. Mich. 2011) ("The weight of Michigan authority supports Defendants' position that negligence per se is not an independent cause of action, but rather a burden-shifting mechanism within the theory of negligence."); *Williams ex rel. Raymond v. Wal-Mart Stores E., L.P.*, 99 So.3d 112, 116 (Miss. 2012) ("[t]he negligence per se doctrine does not create a new cause of action. Rather, it is a form of ordinary negligence, that enables the courts to use a penal statute to define a reasonably prudent person's standard of care.); *Mehl v. Canadian Pac. Ry., Ltd.*, 417 F.Supp.2d 1104, 1118 (D.N.D. 2006) (dismissing a negligence per se claim for failure to state a claim because North Dakota law does not recognize negligence per se claims); *Garland v. Las Vegas Metro. Police Dep't*, No. 2:12-CV-00147-GMN, 2013 WL 1195647, *5 (D. Nev. Mar. 21, 2013) (dismissing with prejudice a negligence per se claim pled separately from ordinary negligence because negligence and negligence per se are one cause of action under Nevada law); *Sipp-Lipscomb v. Einstein Physicians Pennypack Pediatrics*, No. CV 20-1926, 2020 WL 7353105, *3 (E.D. Pa. Dec. 9, 2020) (holding that negligence per se cannot be pled as a separate cause of action, and accordingly, "the court must dismiss the standalone negligence per se claim to permit plaintiffs to plead it as a theory for liability under general negligence"); *Johnson v. Enriquez*, 460 S.W.3d 669 (Tex. App. 2015) ("Negligence per se is not a separate cause of action

independent of a common-law negligence cause of action."); *Parker v. Carilion Clinic*, 819 S.E.2d 809, 824 (Va. 2018) ("the doctrine of negligence per se does not create a cause of action where none otherwise exists"); *Merritt v. United States*, No. 5:18-CV-200, 2020 WL 13336978, *8 (D. Vt. June 26, 2020) ("But the court will not permit Plaintiff to assert a separate claim of "negligence per se" because such a cause of action does not exist and Plaintiff has not demonstrated that the USPS violated a statute or regulation"); *Gilliam v. Dep't of Soc. & Health Servs., Child Protective Servs.*, 89 Wash. App. 569, 950 P.2d 20 (1998) ("Negligence per se is not a separate cause of action. Rather, it is a method of proving negligence through evidence of statutory violations"). Accordingly, it will be recommended that Respironics's motion to dismiss the negligence per se claims asserted under the laws of Alabama, California, Hawaii, Louisiana, Maryland, Massachusetts, Michigan, Mississippi, Nevada, North Dakota, Pennsylvania, Texas, Vermont, Virginia, and Washington be granted.

Two states integrate negligence per se claims into basic negligence claims, but do not mandate that separately pled negligence per se claims be dismissed for that reason.[9] *Cent. Oklahoma Pipeline, Inc. v. Hawk Field Servs., LLC*, 2012 Ark. 157, 400 S.W.3d 701 (Ark. 2012); *Bugg v. Midland Funding, LLC*, No. 6:19-CV-06017-RTD, 2019 WL 3936454 (W.D. Ark. Aug. 19, 2019); *Tolen v. Honeywell*

[9] Arkansas and Illinois.

Int'l, Inc., No. 05-CV-4220-JPG, 2006 WL 3333754, *4 (S.D. Ill. Nov. 16, 2006) ("So long as the plaintiffs have any chance of succeeding on a negligence claim under any theory, negligence per se or otherwise, Counts I and XXI [the negligence per se claims] will remain in this suit.");

Three states do not rule out negligence per se claims as being viable standalone causes of action.[10] In Maine, independent negligence per se actions are viable where the statute they are based on allows for a private right of action. *Elliott v. S.D. Warren Co.*, 134 F.3d 1 (1st Cir. 1998). Minnesota also allows for negligence per se claims to be pled separately – though they are not necessarily independent causes of action. *Perry v. Bay & Bay Transportation Servs., Inc.*, No. CV 22-973 (JRT/ECW), 2023 WL 171885, *8-9 (D. Minn. Jan. 12, 2023); *See also Clean Water & Air Legacy, LLC v. Tofte Wastewater Treatment Ass'n*, No. CV 22-386 (JRT/LIB), 2023 WL 35902 at *7 (D. Minn. Jan. 4, 2023) ("negligence per se may be pleaded separately from negligence"). In Tennessee, negligence per se is not an independent cause of action but nevertheless plaintiffs are obligated to plead it separately. *Nelson v. Inman Homes, Inc.*, No. 1:12-CV-204, 2014 WL 2094327, at *2 (E.D. Tenn. Apr. 17, 2014). Accordingly, it will be recommended that Respironics's motion to dismiss the negligence per se claims asserted under the laws of Maine, Minnesota, and Tennessee be denied.

[10] Maine, Minnesota, and Tennessee.

IV. GROUP THREE ISSUES

A. THE LEARNED INTERMEDIARY DOCTRINE

Respironics requests dismissal of Plaintiffs' failure to warn, negligence, fraud, negligent misrepresentation, unjust enrichment, and consumer protection claims asserted in Counts I, IV, V, XIII, XIV, XVI, and XVII of the PIAC (ECF No. 834) pursuant to the learned intermediary doctrine. Respironics argues that under the learned intermediary doctrine it owed a duty to warn only physicians, not Plaintiffs, regarding the alleged risks of Recalled Devices. Supp. Br. (ECF No. 1346) at 23. Respironics argues that Plaintiffs' claims are barred by the doctrine because Plaintiffs assert that Respironics failed to warn individual Plaintiffs about the alleged danger, and not their physicians. Rather than claim that their physicians would have acted differently following a warning, per Respironics, Plaintiffs claim they themselves would have acted differently. Supp. Br. (ECF No. 1346) at 24. Because Plaintiffs failed to allege any facts relating to warnings received by their doctors, Respironics asserts Plaintiffs' claims fail to establish a "causative nexus" between the alleged failure to warn and any alleged injuries, citing *Adams v. Medtronic, Inc*., No. 4:19-CV-870-SDJ, 2020 WL 5868113 at *5 (E.D. Tex. Oct. 1, 2020). Finally, Respironics asserts that Plaintiffs failed to allege plausible facts that would allow for the inference that Plaintiffs' physicians would have changed their treatment decisions had they received adequate warnings, and this requires dismissal of

Plaintiffs' negligence, implied warranty, fraud, unjust enrichment, and state consumer protection law claims.

In response, Plaintiffs assert that Respironics failed to provide warnings to anyone, let alone Plaintiffs or their physicians, barring invocation of the learned intermediary doctrine. Opp. Br. (ECF No. 1644) at 23 (citing *Walton v. Bayer Corp*., 643 F.3d 994, 1001 (7th Cir. 2011); *Green v. Ethicon, Inc.* 497 F.Supp.3d 364, 369-70 (C.D. Ill. 2020); and *Grubbs v. Smith & Nephew, Inc*., No. 1:19-cv-248, 2020 WL 5305542 at *3-4 (S.D. Ohio Sept. 4, 2020)). Plaintiffs' averments state that Respironics intentionally concealed the defect from consumers to prevent consumers from seeking safer alternatives. *Id*. Plaintiffs encourage the Court to infer from this allegation that if the prescribing physicians had known of the defect in the Recalled Devices, the physicians would not have prescribed the Recalled Devices. *Id*. Finally, Plaintiffs assert that where a manufacturer provides no warnings whatsoever, the learned intermediary doctrine does not apply because it prevents the physician from relaying the information to a patient. *Id*.

At oral argument, the parties spent significant time on the learned intermediary doctrine. Or. Arg. J. 10 (ECF No. 2129) at 110:1-126:25. There, Respironics reiterated the assertion in its briefing that the applicability of the learned intermediary doctrine applies here, despite the complete failure to warn, because the guiding principle is "whether or not the absence of that information would alter the

prescriber's behavior, would have changed either the prescribed course of treatment, would have changed the prescription that the prescriber ultimately ended up with." Or. Arg. J. 10 (ECF No. 2129) at 112:3-112:7. Respironics further asserted that Plaintiffs' failure to allege "any inferences about whether the prescribers would have prescribed CPAPs or ventilators . . . or specific CPAPs or ventilators" requires the dismissal of Plaintiffs' claims. *Id*. at 115:5-115:9. In response, Plaintiffs argued that the doctrine cannot apply absent evidence of an actual warning, and even if Respironics had provided a warning, any responsible doctor would have not prescribed the Recalled Devices. *Id*. at 120:21-120:22, 121:21-121:24.

Primarily, resolution of this issue comes down to a determination of whether Respironics's alleged failure to provide a warning is fatal to the applicability of the learned intermediary doctrine and whether Plaintiffs have properly alleged Plaintiffs' physicians would have changed their treatment plans in light of a warning. Both prongs of the issue are decided in Plaintiff's favor.

First, the parties do not seem to contest that Respironics did not provide notice of the defects in the Devices to anyone. Moreover, Respironics sidesteps the question of whether it provided warnings to physicians entirely. Supp. Br. (ECF No. 1346) at 24. Instead, Respironics asserts that Plaintiffs have only pled that individual Plaintiffs would have made different decisions regarding treatment if they had been provided notice of the degradation. *Id*. (". . . the PIAC alleges that *Plaintiffs – not*

their physicians would have made different decisions if they had received adequate warnings.") (Emphasis in original.)

Plaintiffs request that the Court find that the failure to warn is akin to an inadequate warning under the learned intermediary doctrine because the absence of any warning would be inherently inadequate. *See Baker v. Bayer Healthcare Pharmaceuticals, Inc*., No. C13-0490 TEH, 2013 WL 6698653 at *5 (N.D. Cal. Dec. 19, 2013) (denying motion to dismiss claim under learned intermediary doctrine where Plaintiff alleged "no adequate warning" was provided to her or her physician). "Only when the manufacturer provides the learned intermediary with an adequate warning will the manufacturer's duty be discharged." *Thompson v. DePuy Orthopaedics, Inc*., No. 1:13-CV-00602, 2014 WL 2874268, at *7 (S.D. Ohio June 24, 2014). As the court in *Thompson* explained, "the alleged lack of any warning plausibly shows that the warning did not reach the physician or the patient as is necessary for the learned intermediary doctrine to be applicable."

As to the second prong of the test, whether a warning would have affected a physician's treatment decision, Respironics asserts Plaintiffs have only pled that Plaintiffs themselves would have changed their treatment plans in light of such a warning. Supp. Br. (ECF No. 1346) at 24 (citing PIAC (ECF 834) at ¶ ¶ 576, 614). Respironics contends that Plaintiffs have thus failed to plead a "causative nexus" between Philips's alleged failure to warn and any treating physician's decision. *Id*.

In response, Plaintiffs assert they have pled that prescribing physicians, not just Plaintiffs, would have changed their treatment plans if they had been warned. "Philips intentionally concealed [the defect] from consumers, users, payors, prescribers, and other healthcare providers, including Plaintiffs and their physicians, because to do otherwise would have resulted in users seeking safer alternatives to treat their breathing issues." Opp. Br. (ECF No. 1643) at 23 (citing PIAC (ECF No. 834) at ¶¶ 566, 583, 611, 569, 587, 570). As Plaintiffs argue, "[t]he Court can draw the reasonable inference from these allegations alone, and the Complaint as a whole, that if prescribing physicians had known about the defect, they would not have prescribed the devices." *Id.* Indeed, the mere fact that Philips itself recalled its Devices supports a reasonable inference that a physician would not have prescribed use of the Devices.

The manufacturer has a duty to adequately warn the treating physician, *i.e.*, the learned intermediary. *See McGrain v. C.R. Bard, Inc.*, 551 F.Supp.3d 529, 542 n.12 (E.D. Pa. 2021) (citing *Simon v. Wyeth Pharm*., 989 A.2d 356, 368 (Pa. Super. Ct. 2009). A manufacturer will be held liable for negligence "where it fails to exercise reasonable care to inform the one for whose use the product is supplied of the facts that make the product likely to be dangerous." *Soufflas v. Zimmer, Inc.,* 474 F. Supp. 2d 737, 751 (E.D. Pa. 2007) (quoting *Rosci v. AcroMed, Inc.*, 447 Pa.Super. 403, 422-23 (1995)). In determining if there is a question of fact for the

jury to determine regarding the adequacy of the warning, the Third Circuit considers if there is evidence demonstrating "what a manufacturer knew or should have known about a given risk at the time a patient is prescribed the drug or the cause of action arose, and whether the label warned of that risk." *Id*. (quoting *Avandia*, 817 F.Supp.2d at 547). Where it is alleged that the manufacturer gave no warning at all, it necessarily follows that the learned intermediary doctrine is inapplicable.

On the one hand, Respironics seeks to use the learned intermediary doctrine as a defense to argue that it has met its duty to warn physicians of risks associated with the Recalled Devices. On the other hand, Respironics acknowledges it did not actually provide warnings to physicians regarding the risks associated with the Recalled Devices. Rather, Respironics uses the doctrine to assert that Plaintiffs cannot claim a breach of duty because Respironics only owed physicians, and not Plaintiffs, a duty to warn. Because Plaintiffs allege only that *they* would have made a different decision if warned, rather than alleging that their physicians would have made different decisions, Respironics asserts the learned intermediary doctrine insulates it from liability. Supp. Br. (ECF No. 1346) at 24 (". . . the PIAC alleges that *Plaintiffs – not their physicians* would have made different decisions if they had received adequate warnings.") (emphasis original).

While Respironics presents an interesting argument, it is counterintuitive to allow Respironics the shelter provided by the learned intermediary doctrine when

Respironics appears to concede it did not provide any warnings regarding the Recalled Devices, whether to Plaintiffs or their physicians. Engaging in full discovery, including expert discovery, may assist in determining the applicability, if any, of the learned intermediary doctrine and whether physicians would have recommended against purchasing one of the Recalled Devices after providing a plaintiff with a prescription for a CPAP or BiPap device. Once the record is more fully developed, Respironics may reassert the learned intermediary doctrine at the summary judgment phase. At this stage of the case, however, it is clear that the learned intermediary doctrine is inapplicable. Accordingly, it will be recommended that the Court deny Respironics's motion to dismiss Plaintiffs' failure to warn, negligent misrepresentation, unjust enrichment, and consumer protection law claims under the learned intermediary doctrine.

B. PLAINTIFFS' COMMON LAW FRAUD AND NEGLIGENT MISREPRESENTATION CLAIMS

Respironics asserts that Plaintiffs' common law fraud and negligent misrepresentation claims must be dismissed for the independent reason that the PIAC fails to plead actionable conduct for these claims with the particularity required under Rule 9(b). Supp. Br. (ECF No. 1346) at 42. First, Respironics asserts that Plaintiffs' allegations are so vague that Respironics cannot determine whether Plaintiffs' claims are based upon misrepresentations and omissions or only upon omissions. *Id*. Respironics contends that that Plaintiffs identify no purported false

or misleading statement in violation of what this Court has described as the "rigorous pleading standard." *Id*. at 43 (citing *Bell*, 2018 2447788 at *6 (W.D. Pa. May 31, 2018) (Conti, J.).

Second, Respironics alleges that Plaintiffs have failed to plead facts demonstrating causation for their fraud or negligent misrepresentation claims. *Id*. Respironics asserts Plaintiffs make threadbare allegations that Respironics "concealed and omitted information about the Defect and its related serious health effects" and that Plaintiffs "justifiably and reasonably relied on the omissions." *Id*. Respironics contends that Plaintiffs' failure to plead that they acted in reliance on any representation made by Respironics in using the Recalled Devices is fatal to Plaintiffs' fraud and negligent misrepresentation claims. *Id*. at 44 (citing *Brown v. C.R. Bard*, No. 21-cv-01552, 2022 WL 420914 at *9 (E.D. Pa. Feb. 11, 2022); *Martell v. GM LLC*, 492 F.Supp.3d 1131, 1143-44 (D. Or. 2020); *In re Schering-Plough Corp. Intron/Temodar Consumer Class Action,* No. 2:06-cv-5774 (SRC), 2009 WL 2043604 at *33 (D.N.J. July 10, 2009) (dismissing fraud claims for failure to establish a causal connection between Defendant's conduct and Plaintiff's alleged injury)). As to Plaintiffs' claims of reliance on Defendant's advertisements that Respironics was a "a trusted brand" and "global leader" whose devices were to give "clinically proven" results, Respironics asserts these were mere puffery that cannot form an actionable representation. Reply Br. (ECF No. 1827) at 28-29 (citing

Johnson v. Draeger Safety Diag., Inc., 594 F. App'x 760, 766-67 (3d Cir. 2014); *Fusco v. Uber Tech, Inc*., No. 17-00036, 2018 WL 3618232 at *6-7 (E.D. Pa. Jul. 27, 2018); *Castrol, Inc. v. Pennzoil Co*., 987 F.2d 939, 945 (3d Cir. 1993)).

In response to Respironics's arguments, Plaintiffs assert that they allege each element of common law fraud and negligent misrepresentation by omission. Opp. Br. (ECF No. 1644) at 42. In support of this argument, Plaintiffs rely on *Slippery Rock Area School District v. Tremco, Inc*., No. 15-1020, 2016 WL 3198122 at *12 (W.D. Pa. June 9, 2016). *Id*. at 43. Plaintiffs further assert that the heightened pleading standard of Rule 9(b) requiring plaintiffs to place defendants on notice regarding the precise misconduct charged is "somewhat relaxed" in the context of fraudulent omissions. *Id*. at 43 (citing *Majdipour v. Jaguar Land Rover N. Am., LLC*, No. 2:12-cv-07849 (WHW), 2013 WL 5574626 at *15 (D.N.J. Oct. 9, 2013); *In re Takata Airbag Prod. Liab. Litig*., 464 F.Supp.3d 1291, 1303 (S.D. Fla. 2020)). Finally, Plaintiffs assert that Rule 9(b) does not apply to negligent misrepresentation claims, citing *Sims v. Viacom, Inc*., No. 09-3521, 2009 WL 3856667 at *2 (E.D. Pa. Nov. 17, 2009). *Id*. at 43.

Under Federal Rule of Civil Procedure 9(b), a party alleging fraud must "state with particularity the circumstance constituting fraud or mistake." See F. R. Civ. P. 9(b). The requirements of Rule 9(b) require a party to plead fraud with heightened

particularity as compared to general pleadings under Rule 8 which merely require general statements regarding the claim for relief.

While the Third Circuit has recognized that the particularity requirements of Rule 9(b) may be relaxed where factual information is peculiarly within the defendant's knowledge or control, the Third Circuit has recognized that "even under a relaxed application of Rule 9(b), boilerplate and conclusory allegations will not suffice." *In re Burlington Coat Factory Securities Litigation*, 114 F.3d 1410, 1418 (3d Cir. 1997) (citing *Shapiro v. UJB Financial Corp*., 964 F.2d 272, 285 (3d Cir. 1992)). Where such factual information is peculiarly within the defendant's knowledge or control, "to avoid dismissal in these circumstances, a complaint must delineate at least the nature and scope of plaintiffs' efforts to obtain, before filing the complaint, the information needed to plead with particularity." *Shapiro*, 964 F.2d at 285.

Although details regarding the date, location and time of a representation will meet the particularity requirements of Rule 9(b), a plaintiff is not required to plead those elements so long as a plaintiff can use "alternate means of injecting precision and some measure of substantiation into their allegations of fraud." *In re Rockefeller Center Properties, Inc. Securities Litigation*, 311 F.3d 198, 216 (3d Cir. 2002) (citing *In re Nice Systems*, 135 F.Supp.2d 551, 577 (D.N.J. 2001). References, however,

to marketing and sales materials are insufficient to survive a motion to dismiss. In *Webb v. Volvo*, the Eastern District of Pennsylvania held that the plaintiffs' references to "advertising, marketing promotions, sales materials, owner's manuals materials, safety materials, and warranties" did not demonstrate "a single actual representation by Volvo that [Plaintiff] justifiably relied upon." No. 13-2394, 2018 WL 1470470 at *6 (E.D. Pa. March 26, 2018). Similarly, the Third Circuit has recognized generic references to misrepresentations without pleading the "date, time, and place of the alleged fraud with precision or some measure of substantiation" requires a fraud claim be dismissed. *Frederico v. Home Depot*, 507 F.3d 188, 200 (3d Cir. 2007). Fraud allegations failing to state with specificity "the date, place or time of the allegedly fraudulent actions, or the content of the misrepresentations and the identities of the persons making and receiving the misrepresentations" fail to state a claim for fraud under Rule 9(b). *Vavro v. Albers*, No. 2:05CV321, 2006 WL 2547350 at *17 (W.D. Pa. April 31, 2006).

As to the Plaintiffs' claim of "negligent misrepresentation," however, "there is currently a disagreement among district courts in the Third Circuit regarding whether Rule 9(b) applies. . . ." *McLaughlin v. Bayer Corporation*, 172 F.Supp.3d 804, 829 (E.D. Pa. 2016). The Western District of Pennsylvania adopted the approach of "the majority of Third Circuit courts and decline[d] to apply a heightened pleading standard [under Rule 9(b)] to claims of negligent

misrepresentation." *Cogswell v. Wright Medical Technology*, No. 15-295, 2015 WL 4393385 (W.D. Pa. July 16, 2015).

Applying the heightened pleading standard of Rule 9(b) compels a recommendation that Plaintiffs' common law fraud claim should be dismissed. Plaintiffs do not assert detailed circumstances regarding their experiences with Respironics sufficient to satisfy Rule 9(b). Plaintiffs merely refer to Philips' "marketing materials, advertising, packaging, and/or other communication" but do not attempt to specify the time of these representations or the form in which the Plaintiffs saw them, such as in discussions with their health care providers or through websites or social media. PIAC (ECF No. 834) at ¶ 567. Similarly, Plaintiffs generally assert that they "justifiably and reasonably relied on the omissions by Philips" and assert that "[r]easonable consumers would have been expected to rely on these omissions" and "Philips knew that Plaintiffs and their physicians could not reasonably have been expected" to learn about the alleged defects. *Id*. at ¶ 575. Plaintiffs, however, do not specify the materials they relied on.

While Plaintiffs are not required to allege every material detail of the representation to survive a motion to dismiss, Plaintiffs must still add some precision and substantiation to their claims. Here, Plaintiffs have done neither. The PIAC fails to point to or allege the specific materials Plaintiffs relied on, the medium the materials appeared in, and approximately when Plaintiffs encountered the materials.

Without these allegations, the PIAC fails to meet the requirements of Rule 9(b) to assert an actionable fraud claim. Accordingly, it will be recommended that Respironics's motion as to the fraud claim in Count XIII of the PIAC be granted. Because the negligent misrepresentation claim in Count XIV is not subject to the particularity requirement of Rule 9(b) and Plaintiffs have pled sufficient facts to present a plausible claim for relief for negligent misrepresentation, it will be recommended that Respironics' motion to dismiss Count XIV for failure to comply with pleading standards be denied.

Respironics also provides a state-by-state analysis of the viability of negligent misrepresentation claims. For instance, Respironics argues that Plaintiffs' failure to allege a fiduciary relationship between Plaintiffs and Respironics is fatal to Plaintiffs' negligent misrepresentation claims under the law of several jurisdictions. Supp. Br. (ECF No. 1346) at 44. Respironics also asserts Plaintiffs have failed to demonstrate a confidential or fiduciary relationship between the parties, as required under various states' laws to state a claim for omissions-based fraud and negligent misrepresentation. *Id*.

In response, Plaintiffs assert that Respironics's challenge to eight states is premature and unnecessary. Opp. Br. (ECF No. 1644) at 44. Plaintiffs further assert that Respironics's argument ignores the applicability of Restatement (Second) of Torts § 311 in two jurisdictions and further fails to consider other jurisdictions'

adoption of negligent misrepresentation as a separate cause of action or as part of a negligence claim. *Id.* As to those jurisdictions which Respironics alleges require evidence of a confidential or fiduciary relationship, Plaintiffs similarly assert they have plead an applicable exception - they allege Respironics had knowledge of the defect. *Id*. A review of each of the contested jurisdictions follows.

1. Independent Claims for Negligent Misrepresentation

i. Arkansas

The Arkansas Supreme Court has expressly declined to recognize an independent tort of negligent misrepresentation. *South County, Inc. v. First Western Loan Co*., 871 S.W.2d 325, 326 (Ark. 1994); *see also Henry v. Mitchell*, 428 S.W.3d 454, 464 (Ark. 2013) (declining request to overhaul *South County, Inc*. and recognize negligent misrepresentation); *Curtis Lumber Co., Inc. v. Louisiana Pacific Lumber Corp*., 618 F.3d 762, 775 (8th Cir. 2010) (negligent misrepresentation precluded by Arkansas law). Accordingly, it will be recommended the Court dismiss Plaintiffs' negligent misrepresentation claims under Arkansas law.

ii. Florida

Although Respironics asserts the law in Florida does not permit negligent misrepresentation claims in this context, the law is not clear. The case Respironics cites as support for its argument, *Burrows v. Purchasing Power, LLC*, addresses general negligence claims and does not concern negligent misrepresentation claims.

No. 1:12-cv-22800-UU, 2012 WL 9391827 at *3 (S.D. Fla. 2012). Other cases reflect that the state does recognize a claim for negligent misrepresentation. See *Gilchrist Timber Co. v, ITT Rayonier, Inc*., 696 So.2d 334, 339 (Fla. 1997) (applying claim in breach of contract claim); *Lorber v. Passick as Trustee of Sylvia Passick Revocable Trust*, 327 So.3d 297, 304 (Fla. Dist. Ct. App. 2021) (assessing doctrine in real estate transaction). In the absence of case law clearly precluding such a claim under Florida law, it will be recommended that Respironics's motion to dismiss Plaintiffs' claims for negligent misrepresentation under Florida law be denied.

iii. Idaho

Idaho does not recognize the tort of negligent misrepresentation absent evidence of a professional relationship with an accountant. *Graefe v. Vaughn*, 972 P.2d 317, 319 (Idaho Ct. App. 1999); *Duffin v. Idaho Crop Imp. Ass'n*, 895 P.2d 1195, 1203 (Idaho 1995). Accordingly, because there is no professional relationship at issue here, it will be recommended that the Court dismiss Plaintiffs' claims for negligent misrepresentation arising under Idaho law.

iv. Indiana

The law in Indiana is generally not clear as to whether a negligent misrepresentation claim can exist outside the context of a business or employment relationship. *Tri-Professional Realty, Inc. v. Hillenburg*, 669 N.E.2d 1064, 1068 (Ind. Ct. App. 1996) ("The condition of Indiana law regarding the tort of negligent

misrepresentation has been aptly described as one of 'relative chaos.'"). To date, Indiana courts have not recognized that a duty exists to support the tort of negligent misrepresentation outside the limited context of an employment relationship. *Id*.; *see also Thomas v. Lewis Engineering, Inc*., 848 N.E.2d 758, 760 (Ind. Ct. App. 2006) ("Indiana has not adopted Restatement Section 552 without limitation. Indeed, the condition of Indiana law regarding the tort of negligent misrepresentation has been aptly described as one of "relative chaos."). Thus, Indiana courts have limited the scope of a claim for negligent misrepresentation. In light of the limitations the Indiana Court of Appeals has placed on claims for negligent misrepresentation, it will be recommended that Respironics's motion to dismiss Plaintiffs' negligent misrepresentation claims arising under Indiana law be granted.

v. Maine

In *Tardy v. Eli Lily and Co.*, No. CV-03-538, 2004 WL 1925536, at *4 (Me. Aug. 3, 2004), the Superior Court of Maine limited negligent misrepresentation claims to business transactions. Plaintiffs have not presented contrary authority under the law of Maine that would support their argument. The case Plaintiffs rely on, *Dow v. Maier*, 2000 WL 33675683, *3 (Me. Super. Ct. Mar. 15, 2000), addresses a narrow exception to this requirement for claims between a physician and patient that is not presented by the present circumstances. Opp. Br. (ECF No. 1644) at 62.

Accordingly, it will be recommended that Plaintiffs' claim for negligent misrepresentation claim under the law of Maine be dismissed.

vi. Minnesota

While Respironics asserts that negligent misrepresentation is only available in the context of a business relationship in Minnesota, *see* Supp. Br. (ECF No. 1346) at 65, case law demonstrates that courts have recognized the claim in additional contexts. *Reichel Investments, L.P. v. Reichel*, No. A15-1724, 2016 WL 3884552 at *4 (Minn. Ct. App. July 18, 2016) (analyzing negligent misrepresentation claim in investment client context); *Pemrick v. Bucher,* No. A16-0850, 2017 WL 390152 at *4 (Minn. Ct. App. 2017) (applying doctrine in personal injury claim while ultimately holding it was barred by collateral estoppel). Thus, the law is not as clear as Respironics asserts. Considering this lack of clarity and the deferential standard of a motion to dismiss, it will be recommended that Respironics's motion to dismiss Plaintiffs' negligent misrepresentation claims arising under Minnesota law be denied.

vii. North Carolina

North Carolina recognizes the tort of negligent misrepresentation but only "where pecuniary loss results from the supplying of false information to others for the purpose of guiding them in their business transactions." *See Driver v. Burlington Aviation, Inc.*, 430 S.E.2d 476, 480 (N.C. Ct. App.1993). As Plaintiffs assert

personal injury claims, Plaintiffs' negligent misrepresentation claim is unsupported by North Carolina law. Accordingly, it will be recommended that the Court grant Respironics's motion to dismiss Plaintiffs' negligent misrepresentation claims arising under North Carolina law.

viii. Virginia

"[T]he Virginia Supreme Court has not recognized the tort of negligent misrepresentation." *Haigh v. Matsushita Elec. Corp. of Am*., 676 F. Supp. 1332, 1349 (E.D. Va. 1987). Accordingly, it will be recommended that Respironics's motion to dismiss Plaintiffs' negligent misrepresentation claims arising under Virginia law be granted.

2. Jurisdictions Requiring a Confidential or Fiduciary Relationship

In support of its motion to dismiss Plaintiffs' negligent misrepresentation claims, Respironics further avers that Plaintiffs fail to allege a fiduciary or similar relationship with Respironics sufficient to impose on Respironics a duty to disclose information to Plaintiffs under the laws of several jurisdictions. Supp. Br. (ECF No. 1346) at 44. Respironics relies on *Slippery Rock Area School District v. Tremco Inc*., Civ. A. No. 15-1020, 2016 WL 3198122 at *12 (W.D. Pa. June 9, 2016), and *Cohen v. Subaru of America, Inc*., No. 1:20-cv-08442-JHR-AMD, 2022 WL 721307 (D.N.J. March 10, 2022). *Id*.

In response, Plaintiffs assert that each state identified by Respironics recognizes the duty to disclose absent a confidential or fiduciary relationship where

"(1) one party has superior knowledge; (2) the defect goes to health and safety; or (3) the defendant partially disclosed facts but withheld information that would have been material." Opp. Br. (ECF No. 1644) at 44. Plaintiffs allege they have pled each of these elements. *Id.* In its reply brief, Respironics avers that Plaintiffs' claims regarding this exception to the confidential or fiduciary relationship requirement giving rise to a duty to disclose is not supported by the case law Plaintiffs cite. Repl. Br. (ECF No. 1827) at 28. Moreover, as to the third exception regarding partial disclosure, Respironics asserts Plaintiffs cannot rely on this exception because Plaintiffs fail to identify any statement made by Respironics in the PIAC. *Id*.

i. Alabama

The case on which Plaintiffs rely on in support of their argument that Respironics was required to disclose the safety risks of the Recalled Devices to Plaintiffs because they had "a specific defect that affect[s] health or safety" is not dispositive of this issue. *See Hughes v. Hertz Corp*., 670 So.2d 882, 888 (Ala. 1995). Rather, the Supreme Court of Alabama in that case recognized the doctrine had "previously been applied in cases involving the sale of used real estate" and narrowly expanded the doctrine to apply to "the sale of a used car." *Id*. Thus, there is no persuasive authority applying Alabama law that Respironics owed Plaintiffs a duty to disclose defects in the Devices.

Nor is there authority that would impose a duty to disclose under the circumstances presented here. The District Court of New Jersey's opinion in *Cohen* addressed this exact question in an arms-length relationship similar to the parties' relationship here. There, applying Alabama law, the court recognized "'[m]ere silence is not fraudulent in the absence of a duty to disclose. A duty to disclose may arise from the particular circumstances of the case, from a confidential relationship, or from a request for information.'" *Cohen*, 2022 WL 721307 at *20.

Plaintiffs here do not allege facts giving rise to an inference that there was a confidential or fiduciary relationship between Plaintiffs and Respironics. Accordingly, it will be recommended that the Court grant Respironics's motion to dismiss Plaintiffs' negligent misrepresentation claims arising under Alabama law.

ii. Connecticut

Courts interpreting Connecticut law have held "'[n]ondisclosure may . . . amount to fraud when there is a failure to disclose known facts under circumstances that impose a duty to speak.'" *Est. of Axelrod v. Flannery*, 476 F.Supp.2d 188, 194 (D. Conn. 2007) (quoting *Dockter v. Slowik*, 881 A.2d 479 (Conn. App. Ct. 2005)). Under Connecticut law, such a duty may arise in the context of a fiduciary relationship, *id*. at 194 (citing *Falls Church Group, Ltd. v. Tyler, Cooper and Alcorn, LLP*, 874 A.2d 266 (Conn. App. Ct. 2005)), or in a real estate transaction. *Wedig v. Brinster,* 469 A.2d 783, 788 (Conn. App. Ct. 1983); Opp. Br. (ECF No. 1644) at 60.

But no authority has been presented that recognizes an actionable negligent representation claim under the circumstances presented here. Accordingly, it will be recommended that the negligent misrepresentation claim asserted under Connecticut law be dismissed.

iii. Delaware

Generally, Delaware "does not recognize a duty to disclose information except (1) in the context of a contractual or fiduciary relationship, (2) when disclosures are necessary to prevent statements actually made from being misleading, or (3) if [one party] knows that the other is about to enter into [a contract] under a mistake . . . and that the other, because of the relationship between them, the customs of the trade or other objective circumstances, would reasonably expect a disclosure of those facts." *Rohm and Haas Electronic Materials, LLC v. Honeywell Intern., Inc*., No. 06-297-GMS, 2009 WL 1033651 at *7 (D. Del. Apr. 16, 2009) (citing *In re Student Fin. Corp*., No. 03–507–JJF, 2004 WL 609329, at *5 (D. Del. Mar.23, 2004)). Whether one of these circumstances is present cannot be determined definitively from the pleadings. The PIAC, however, does contain sufficient averments from which it may be reasonably inferred that Respironics should have known that an individual was purchasing one of its Devices under the mistaken belief that it was safe for its

intended purpose. Accordingly, it will be recommended that Respironics's motion to dismiss the negligent misrepresentation claim under Delaware law be denied.

iv. Florida

Under Florida law, negligent misrepresentation claims require reliance on an affirmative misrepresentation or a fiduciary relationship that would create a duty to disclose. In a commercial transaction in which the parties are dealing at arm's length, "a fiduciary relationship does not exist because there is no duty imposed on either party to protect or benefit the other." *R.J. Reynolds Tobacco Co. v. Whitmire*, 260 So.3d 536, 538–39 (Fla. Dist. Ct. App. 2018) (citations and quotations omitted). Plaintiffs, however, point to several cases demonstrating an exception to this duty to disclose which may be present here. See *Nessim v. DeLoache*, 384 So.2d 1341, 1344 (Fla. App. 1980) ("The classic illustration of fraud is where one party having superior knowledge intentionally fails to disclose a material fact."); *Nicholson v. Kellin*, 481 So.2d 931, 936 (Fla. Dist. Ct. App. 1985) ("[E]ven assuming that a party to a transaction owes no duty to disclose facts within his knowledge or to answer inquiries respecting such facts, if he undertakes to do so he must disclose the whole truth.") *S.K.Y. Mgmt. LLC v. Greenshoe, Ltd.*, No. 06-21722-CIV-LENARD/TORRES, 2007 WL 9701121, at *3 (S.D. Fla. Mar. 11, 2007) (noting the duty to disclose "arises only where there [is] a fiduciary or other special relationship exists or where one party clearly has superior knowledge and the other party has no

opportunity to investigate"). Accordingly, it will be recommended that the Court deny Respironics's motion to dismiss Plaintiffs' negligent misrepresentation claims under Florida law.

v. Georgia

Under Georgia law, "[s]uppression of a material fact which a party is under an obligation to communicate constitutes fraud. The obligation to communicate may arise from the confidential relations of the parties or from the particular circumstances of the case." Ga. Code Ann. § 23-2-53. The particular circumstances of a case, "may give rise to an obligation to communicate where there is concealment of 'intrinsic qualities of the article which the other party by the exercise of ordinary prudence and caution could not discover." *Amin v. Mercedes-Benz USA, LLC*, 301 F.Supp.3d 1277, 1296 (N.D. Ga. 2018). *See also Jordan v. Flynt*, 240 S.E.2d 858, 863 (Ga. 1977) (noting if a party "speaks at all, he must make a full and fair disclosure."). Under these circumstances, it will be recommended that Respironics's motion to dismiss Plaintiffs' negligent misrepresentation claims under Georgia law be denied.

vi. **Illinois**

Illinois recognizes a cause of action for negligent misrepresentation. *See, e.g., Capiccioni v. Brennan Naperville, Inc.,* 791 N.E.2d 553, 562 (Ill. App.. Ct. 2003). Under Illinois law, negligent misrepresentation consists of: (1) a false statement of a material fact; (2) carelessness or negligence in ascertaining the truth

of the statement by the party making it; (3) an intention to induce the other party to act; (4) action by the other party in reliance on the truth of the statement; and (5) damage to the other party resulting from such reliance when the party making the statement is under a duty to communicate accurate information." *Id.* The PIAC alleges facts sufficient to support an inference that each of these elements is present here. In particular, Plaintiffs have adequately alleged that Respironics had exclusive knowledge of the alleged defects associated with the Recalled Devices sufficient to imply a duty to disclose. Accordingly, it will be recommended that Respironics's motion to dismiss the negligent misrepresentation claim under Illinois law be denied.

vii. Iowa

The Court agrees with Plaintiffs that under Iowa law, Respironics owed a duty to disclose to Plaintiffs. In *Wright v. Brooke Group Ltd*., the Iowa Supreme Court recognized that "a manufacturer's failure to warn or to disclose material information does not give rise to a fraud claim when the relationship between a plaintiff and a defendant is solely that of a customer/buyer and manufacturer." 652 N.W.2d 159, 177 (Iowa 2002). However, the Iowa Supreme Court noted this principle is subject to two exceptions, including "where the manufacturer (1) has made misleading statements of fact intended to influence customers, or (2) has made true statements of fact designed to influence consumers and subsequently acquires information rendering the prior statements untrue or misleading." *Id*.

Plaintiffs have alleged sufficient facts to demonstrate at this stage that Respironics owed a duty to disclose information regarding the Recalled Devices once it learned of the risks associated with the Devices. Accordingly, it will be recommended that the Court deny Respironics's motion to dismiss the negligent misrepresentation claim under Iowa law.

viii. Maryland

The Maryland Court of Appeals has recognized a negligent misrepresentation claim is actionable "if there is more than a mere failure to reveal facts *i.e*. if, with the intent to mislead, there is a statement or other conduct which prevents another from acquiring knowledge of a fact . . . ." *Brass Metal Prod., Inc. v. E-J Enter., Inc*., 984 A.2d 361, 387 n.22 (Md. 2009) (citing *Fegas v. Sherrill*, 147 A.2d 223 (Md. 1958)). Finding here that Plaintiffs have alleged Respironics failed to disclose information that would have affected Plaintiffs' decision to purchase the Recalled Devices, it will be recommended that the Court deny Respironics's motion to dismiss Plaintiffs' negligent misrepresentation claims arising under Maryland law.

ix. Massachusetts

Under Massachusetts common law, "'[t]o show fraud by omission, the plaintiff must allege 'both concealment of material information and a duty requiring disclosure.' " *Costa v. FCA US LLC*, 542 F.Supp.3d 83, 101 (D. Mass. 2021). The Massachusetts Court of Appeals has recognized that a duty to disclose exists where

"there are matters known to the speaker that he knows to be necessary to prevent his partial or ambiguous statement of the facts from being misleading." *Stolzoff v. Waste Sys. Int'l, Inc*., 792 N.E.2d 1031, 1044 (Mass. App. Ct. 2003). Plaintiffs have demonstrated that Respironics may have owed a duty to disclose under circumstances giving rise to a claim actionable under Massachusetts law. Accordingly, it will be recommended that the Court deny Respironics's motion to dismiss Plaintiffs' negligent misrepresentation claims arising under Massachusetts law.

x. Mississippi

While both parties cite the Mississippi Court of Appeals' opinion in *Poe v. Summers* as support for their arguments, the Court finds the opinion supports Plaintiffs' argument. 11 So.3d 129, 134 (Miss. Ct. App. 2009) (citing 37 Am.Jur.2d Fraud and Deceit § 204) (2001)). There, the Court of Appeals of Mississippi noted a duty to disclose exists absent a special relationship when "the fact concealed is peculiarly within the knowledge of one party and of such a nature that the other party is justified in assuming its nonexistence, there is a duty of disclosure, and a deliberate suppression of such a fact constitutes fraud." *Id*. Plaintiffs have alleged that Respironics had superior knowledge of the defects prior to Plaintiffs' purchase of the Recalled Devices. Accordingly, it will be recommended that the Court deny the

motion to dismiss Plaintiffs' negligent misrepresentation claim under Mississippi law.

xi. Nevada

The Court is persuaded that Nevada does recognize broader requirements to disclose than Respironics alleges. Specifically applicable here, the Supreme Court of Nevada has recognized the "[n]ondisclosure will become the equivalent of fraudulent concealment when it becomes the duty of a person to speak in order that the party with whom he is dealing may be placed on an equal footing with him." *Dow Chem. Co. v. Mahlum*, 970 P.2d 98, 110 (Nev. 1998). It will be recommended that the Court deny Respironics's motion to dismiss Plaintiffs' negligent misrepresentation claims arising under Nevada law.

xii. New Jersey

New Jersey cases hold that a party is required to disclose information even in the absence of a special relationship where such a disclosure is necessary to make a prior representation true. See *Ponzio v. Mercedes-Benz USA, LLC*, 447 F. Supp. 3d 194, 234 (D.N.J. 2020); *Amato v. Subaru of Am., Inc*., No. 18-16118, 2019 WL 6607148, at *21 (D.N.J. Dec. 5, 2019). Because Plaintiffs have alleged that Respironics failed to supplement disclosures following its knowledge of the alleged defects, it will be recommended that the Court deny Respironics's motion to dismiss the negligent misrepresentation claim under New Jersey law.

xiii. New York

"To state a cause of action for negligent misrepresentation, . . . the plaintiff must allege '(1) the existence of a special or privity-like relationship imposing a duty on the defendant to impart correct information to the plaintiff; (2) that the information was incorrect; and (3) reasonable reliance on the information.'" *Ginsburg Dev. Cos., LLC v. Carbone*, 134 A.D.3d 890, 894, 22 N.Y.S.3d 485 (2d Dep't 2015). "To allege a special relationship, [the plaintiff] must establish something beyond an ordinary arm's length transaction." *Naughright v. Weiss*, 826 F. Supp. 2d 676, 688 (S.D.N.Y. 2011). In order to find that reliance on the information is justified, there must be a "closer degree of trust between the parties than that of the ordinary buyer and seller[.]" *Dallas Aerospace, Inc. v. CIS Air Corp*., 352 F.3d 775, 788 (2d Cir. 2003); see also *Kimmell v. Schaefer*, 89 N.Y.2d 257, 263, 652 N.Y.S.2d 715, 675 N.E.2d 450 (1996) ("[L]iability for negligent misrepresentation has been imposed only on those persons who possess unique or specialized expertise, or who are in a special position of confidence and trust with the injured party such that reliance on the negligent misrepresentation is justified."). Such a relationship has not been alleged in the PIAC. Accordingly, it will be recommended that the Court grant Respironics's motion to dismiss the negligent misrepresentation claim under New York law.

xiv. Ohio

Ohio law recognizes that "full disclosure may be required of a party to a business transaction where such disclosure is necessary to dispel misleading impressions that are or might have been created by partial revelation of the facts." *Stuckey v. Online Resources Corp*., 819 F.Supp.2d 673, 686–87 (S.D. Ohio 2011). Considered in the light of the PIAC, this holding militates against dismissing the negligent misrepresentation claim at this stage of the proceedings. Accordingly, it will be recommended that the Court deny Respironics's motion to dismiss Plaintiffs' negligent misrepresentation claims arising under Ohio law.

xv. Oregon

Gregory v. Novak, 855 P.2d 1142, 1144 (Or. Ct. App. 1993), recognized that "one who makes a representation that is misleading because it is in the nature of a 'half-truth' assumes the obligation to make a full and fair disclosure of the whole truth." *Id*. In light of this holding and the PIAC allegations, it will be recommended that the Court deny Respironics's motion to dismiss Plaintiffs' negligent misrepresentation claims arising under Oregon law.

xvi. Pennsylvania

Pennsylvania law supports a duty to disclose where on party has superior knowledge of the facts material to a transaction. *See Gaines v. Krawczyk*, 354 F.Supp.2d 573, 586 (W.D. Pa. 2004); *In re Volkswagen Timing Chain Prod. Liab. Litig*., No. CV 16-2765 (JLL), 2017 WL 1902160, at *19 (D.N.J. May 8, 2017). As Plaintiffs have sufficiently alleged the parties had unequal information regarding the

Recalled Devices, it will be recommended that the Court deny Respironics's motion to dismiss Plaintiffs' negligent misrepresentation claims arising under Pennsylvania law.

xvii. South Carolina

South Carolina appears to recognize a duty to disclose safety information under the circumstances akin to those presented here. *See Fisher v. Pelstring*, 817 F.Supp.2d 791, 822–24 (D.S.C. 2011). Accordingly, it will be recommended that the Court deny Respironics's motion to dismiss Plaintiffs' negligent misrepresentation claims arising under South Carolina law.

xviii. South Dakota

The law in South Dakota is that there is no duty to disclose absent a confidential or fiduciary relationship. *See Taggart v. Ford Motor Credit Co*., 462 N.W.2d 493, 504 (S.D. 1990). Accordingly, it will be recommended that the Court grant Respironics's motion to dismiss Plaintiffs' negligent misrepresentation claims under South Dakota law.

xix. Texas

Respironics asserts under Texas law a duty to disclose arises (1) when there is a fiduciary relationship; (2) when one voluntarily discloses information, the whole truth must be disclosed; (3) when one makes a representation, new information must be disclosed when that new information makes the earlier representation misleading or untrue; and (4) when one makes a partial disclosure and conveys a false

impression. *Hoffman v. AmericaHomeKey, Inc*., 23 F.Supp.3d 734, 745 (N.D. Tex. 2014) (quoting *Hoggett v. Brown*, 971 S.W.2d 472, 487 (Tex. Ct. App. 1997)). Plaintiffs rely on *White v. Zhou Pei*, 452 S.W.3d 527, 537-38 (Tex. Ct. App. 2014) (one party has superior knowledge); *Yoon v. Yoo*, No. 3:15-cv-303-P, 2016 WL 4801314 (N.D. Tex. Feb. 24, 2016) (partial disclosure); *Highland Crusader Offshore Partners, L.P. v. Lifecare Holdings, Inc*., No. 3:08-CV-0102-B, 2009 WL 1065212 at *6 (N.D. Tex. Apr. 21, 2009) (health and safety exception); *Kirkbride v. Kroger Co*., No. 2:21-cv-0022, 2022 WL 2703960 at *8 (S.D. Ohio July 12, 2022) (applying Texas law, partial disclosure); *Conestoga Tr. Servs., LLC, Tr. of Conestoga Tr. v. Focus Med. Underwriters, LLC*, No. 14-20-00302-CV, 2022 WL 599344 at *3 (Tex. App. Mar. 1, 2022) (superior knowledge); Opp. Br. (ECF No. 1644) at 61.

Plaintiffs have demonstrated that several exceptions, such as partial disclosure and superior knowledge, may be present here. Accordingly, it will be recommended that the Court deny Respironics's motion to dismiss Plaintiffs' negligent misrepresentation claims under Texas law.

C. PLAINTIFFS' CONSUMER PROTECTION LAW CLAIMS

In support of its motion to dismiss, Respironics avers that each of Plaintiffs' claims arising under individual states' consumer protection acts fail as a matter of law. Supp. Br. (ECF No. 1346) at 45. First, Respironics generally asserts that Plaintiffs' "attempt to allege causes of action . . . by perfunctorily listing the citations

to sixty-five distinct consumer statutes" is insufficient to state a claim. *Id*. Respironics relies on *Papuerllo v. State Farm Fire & Cas. Co*. as support for its argument that bare citation of a statute is insufficient to allege the elements necessary to state a plausible claim for relief. *Id*.; 144 F.Supp.3d 746, 776-77 (W.D. Pa. 2015).

In addition to arguing Plaintiffs' claims are insufficient under Rule 9(b), Respironics asserts several criteria under which it asserts that Plaintiffs' claims should be dismissed.[11] As Respironics admits these claims overlap and affect the same jurisdictions, the arguments for dismissal and the parties' responses will be reviewed in order.,.

1. Jurisdictions Barring Statutory Consumer Protection Claims for Personal Injuries

Respironics asserts that claims for personal injuries like the ones Plaintiffs assert are barred under the consumer statutes of fourteen jurisdictions. Supp. Br. (ECF No. 1346) at 48. At oral argument, Plaintiffs' counsel sought to distinguish Plaintiffs' personal injury claims for economic losses from non-economic losses that would be barred under certain jurisdictions' consumer protection laws. ECF No.

[11] A review of the statutes and judicial interpretations reveals courts have not uniformly applied the requirements of Rule 9(b) to these statutory consumer protection claims.

2129 at 153:8-153:18. The assessment of the consumer protection act claims will be undertaken with that point in mind.

i. **Alaska**

The Alaska Supreme Court has held that claims for personal injury are prohibited under the Alaska Unfair Trade Practices and Consumer Protection Act, explaining that "the private cause of action available under the UTPA conflicts in too many ways with the traditional claim for personal injury or wrongful death for us to assume, without clear legislative direction, that the legislature intended the act to provide an alternative vehicle for such suits." *Donahue v. Ledgends, Inc*., 331 P.3d 342, 354 (Ak. 2014). Accordingly, it will be recommended that the Court grant Respironics's motion to dismiss Plaintiffs' consumer protection claims arising under Alaska law.

ii. Florida

The Florida Deceptive and Unfair Trade Practices Act, West's Florida Statutes Annotated § 501.212, expressly exempts personal injury claims, noting the Act does not apply to "a claim for personal injury or death." *Id*. Furthermore, Florida courts have routinely held that the Act bars personal injury claims. *See, e.g., Davis v. Boston Scientific*, No. 2:17-cv-682-FtM-38CM, 2018 WL 2183885 at *8 (M.D. Fla. May 11, 2018) ("Though FDUTPA prohibits 'unfair or deceptive acts or practices in the conduct of any trade or commerce,' it does not apply to claims for personal

injury or death"); *Fojtasek v. NCL (Bahamas) Ltd*., 613 F.Supp.2d 1351, 1356 (S.D. Fla. 2009) ("FDUTPA specifically precludes a plaintiff from bringing a claim for personal injury or death").

As Plaintiffs observe, however, Respironics has addressed only Plaintiffs' claims asserted under Fla. Stat. Ann. §501.201, et seq. (FDUTPA), and not Plaintiffs' claims under Fla. Stat. Ann. §§817.06 and 817.41, dealing with misleading advertising. Neither statute contains a limitation against personal injury claims. Accordingly, it will be recommended that the Court grant Respironics's motion to dismiss the claim asserted under the FDUPTA but deny the motion with respect to the claims asserted under Fla. Stat. Ann. §§817.06 and 817.41.

iii. Hawaii

Plaintiffs cannot recover for personal injuries under Hawaii's consumer protection laws. *Heejoon Chung v. U.S.. Bank, N.*A., 250 F.Supp.3d 658, 691, n. 28 (D. Hawaii 2017) ("Haw. Rev. Stat. Chapter 480 precludes damages for personal injury and emotional distress"). *See also Zanakis-Pico v. Cutter Dodge, Inc*., 98 Hawai'i 309, 319, 47 P.3d 1222, 1232 (2002)); *Beerman v. Toro Mfg. Corp*., 1 Haw. App. 111, 117, 615 P.2d 749, 754 (1980).) Accordingly, it will be recommended that the Court

grant Respironics's motion to dismiss the claim under the Hawaii consumer protection law.

iv. Iowa

The Iowa Consumer Fraud Act, Iowa Code § 714H.5, does not apply to claims for personal injuries. The statute provides that a consumer may recover for claims for "ascertainable loss of money or property as the result of a prohibited practice or act in violation of this chapter." *See id.* Further, the definitions portion of the statute provides that "actual damages" recoverable under the act "does not include damages for bodily injury, pain and suffering, mental distress, or loss of consortium, loss of life, or loss of enjoyment of life." § 714H.2. Thus, it will be recommended that the Court grant Respironics's motion to dismiss Plaintiffs' claims under the Iowa Consumer Fraud Act.

v. Maine

Respironics correctly asserts that Plaintiffs' claims are barred under the Maine consumer protection statutes because the act provides only for recovery of damages resulting from "loss of money or property, real or personal." Maine Revised Statutes § 213(1). Further, both the case law cited by Respironics and case law interpreting this section agree it applies to loss of money or property only. *Benner v. Wells Fargo Bank, N.A.,* No. 2:16-cv-00467-NT, 2018 WL 1548683 at *13 (D. Maine March 29, 2018) ("Damages under the UTPA are limited to 'a loss of money or property that results from the violation.'"); *McGahey v. Federal National Mortgage Association*,

266 F.Supp.3d 421 (D. Me. 2017) (holding damages under UTPA are limited to loss of money or property); *Parker v. Ayre*, 612 A.2d 1283 (Me. 1992) (recognizing private relief is available under the UTPA only for loss of money or property). Accordingly, it will be recommended that the Court grant Respironics's motion to dismiss Plaintiffs' claims under the Maine Unfair Trade Practices Act.

vi. Nebraska

The Nebraska Consumer Protection Act does not provide for recovery for personal injuries. Instead, the statute provides recovery only for individuals "injured in his or her business or property." Nebraska Consumer Protection Act § 59-1609. However, Respironics does not cite case law interpreting this section to definitively assert that personal injury claims would be not included. As Plaintiffs do not contest Respironics's position as to the Nebraska Consumer Protection Act, it will be recommended that the Court grant Respironics's motion to dismiss Plaintiffs' claims under Nev. Rev. Stat. §59-1601, et seq.

vii. New Mexico

Plaintiffs cannot seek recovery of personal injury damages under New Mexico's consumer protection statutes. *Pena v. Scrip, Inc*., No. 11-1102-GBW/WDS, 2013 WL 12334164 at *4-5 (D. N.M. March 22, 2013) ("The construction of the UPA indicates that it was not intended to provide a remedy for personal injuries."). Accordingly, it will be recommended that the Court grant

Respironics's motion to dismiss Plaintiffs' claims arising under the New Mexico UPA.

viii. Ohio

Plaintiffs' claims for personal injury are barred under the Ohio Consumer Sales Practice Act. *See* Ohio Revised Code Annotated § 1345.12(C). ("[The Act] does not apply to . . . "claims for personal injury or death."). Further, the case Respironics cites, *Kelley v. Insys Therapeutics, Inc*., notes that this limitation will apply where "the gravamen of the case" is the plaintiffs' alleged physical harm suffered as a result of a violation of the consumer protection statute. No. 3:18CV1774, 2019 WL 329600 at *7 (N.D. Oh. Jan. 25, 2019).

In response, Plaintiffs rely on Ohio Rev. Code Ann. §1345.01, et seq. *Whitaker v. M.T. Auto., Inc*., 855 N.E.2d 825, 833 (Ohio 2006) (claims only barred if the statutory violation requires proof of a personal injury; claims permitted where a plaintiff's injuries are the result of a violation); Opp. Br. (ECF No. 1644) at 66. Although the Supreme Court of Ohio's opinion in *Whitaker* is informative, the Court does not believe it is as dispositive as Plaintiffs assert. While Plaintiffs assert the holding stands to permit "claims . . . where a plaintiff's injuries are the result of the violation," the Supreme Court of Ohio limited its review to damages permitted, rather than claims. 855 N.E.2d at 833. There, in answering the question of whether § 1345.12 bars "recovery of certain *damages* that are also recoverable in personal

injury claims" the Court answered the question in the negative. *Id*. (emphasis added). Thus, Plaintiffs appear to collapse the court's permitting personal injury damages to arise from a violation of § 1345.12 with allowing personal injury claims to be permitted under the statute. This is a distinction the Supreme Court of Ohio expressly addressed, noting "the General Assembly chose the word 'claims' instead of 'damages'" for § 1345.12. 855 N.E.2d 825 at 184.

Claims for personal injuries may not be brought under § 1345.12 given the clear text of the statute. Accordingly, it will be recommended that the Court grant Respironics's motion to dismiss Plaintiffs' claims arising under Ohio consumer protection act.

ix. Oregon

Oregon's Unfair Trade Practices Act, Or. Rev. Stat. Ann. § 646.638, bars claims for noneconomic injuries. *See Pearson v. Philip Morris, Inc*., 361 P.3d 3, 23 (Or. 2015); *Parada v. MJ's Labor Services, Inc*., No. 2:17-cv-00521-SU, 2019 WL 4145224 at *7 (D. Oregon August 30, 2019) (denying recovery for noneconomic losses); *Hamilton v. Gen. Mills. Inc*., No. 6:16-cv-382-MC, 2016 WL 4060310 at *4 (D. Or. 2016) (("[The UTPA] standard precludes claims for personal injury and noneconomic losses such as physical pain, emotional distress, or humiliation from being brought under the UTPA."). Accordingly, it will be recommended that the

Court grant Respironics's motion to dismiss Plaintiffs' claims arising under Oregon's Unfair Trade Practices Act.

x. Pennsylvania

Pennsylvania likewise does not provide for recovery for personal injuries under its Unfair Trade Practices and Consumer Protection Law. *See King v. Hyundai Motor Manufacturing America*, No. 1:18-CV-450, 2019 WL 458477 at *3 (Jan. 3, 2019) (recommending granting motion to dismiss on plaintiffs' personal injury claims under UTPCPL). Accordingly, it will be recommended that the Court grant Respironics's motion to dismiss Plaintiffs' UTPCPL claim asserted under Pennsylvania law.

xi. South Carolina

Respironics has not clearly demonstrated that Plaintiffs' claims to recover personal injury damages arising under the South Carolina Unfair Trade Practices Act, S.C. Code Ann. § 39-5-10, et seq., should be dismissed. The case Respironics cites in support of its argument, *Jones v. Ram Medical, Inc*., provides that a party may recover claims for personal injuries under the act. 807 F.Supp.2d 501, 510 (D. S.C. 2011). There, the court held that the plaintiffs stated a claim for recovery under the act in their allegations of personal injuries after assessing precedent that allowed plaintiffs to recover for "their medical costs, lost earnings, and any other alleged out of pocket expenses" under the SCUTPA. *Id*. While the language of the SCUTPA

provides for recovery for losses of "money and property" as a result of a violation of the statute, the *Jones* opinion raises doubts regarding whether the statute clearly exempts claims for personal injuries. SCUTPA § 39-5-140.

At oral argument, Plaintiffs' counsel relied on *Little v. Brown & Williamson Tobacco Corp.,* No. C.A. 2:98-1879-23, 1999 WL 33291385, at *11 (D.S.C. Mar. 3, 1999), to assert that South Carolina distinguishes between economic losses associated with personal injury claims, such as medical costs and lost earnings, through the court's holding that a plaintiff may recover for such economic losses in a personal injury action. Or. Arg. J. 10 (ECF No. 2129) at 153:1-9. This distinction is also reflected in Paragraph 616 of the PIAC, alleging that Plaintiffs were "injured and suffered ascertainable losses of money or property by Philips's wrongful conduct." PIAC (ECF No. 834) at ¶ 616. Accordingly, it will be recommended that Respironics's motion to dismiss Plaintiffs' claims under the SCUTPA be denied.

xii. Tennessee

A Tennessee Consumer Protection Act claim must be dismissed where a plaintiff "seeks to recover for injuries to his person resulting from [a defendant's] alleged violation of the TCPA." *Orr v. Ethicon, Inc*., No. 2:20-CV-110-TAV-HBG, 2020 WL 9073528, at *3 (E.D. Tenn. Sept. 11, 2020). Plaintiffs do not contest the limitation on claims under the TCPA asserted by Respironics. *See* Opp. Br. (ECF

No. 1644) at 66, Chart 12. Accordingly, it will be recommended that the Court grant Respironics's motion to dismiss Plaintiffs' claims under the TCPA.

xiii. Texas

Respironics assertion that Texas law does not permit a claim for personal injury damages under its consumer protection statutes is not contested. Accordingly, it will be recommended that the Court grant Respironics's motion to dismiss Plaintiffs' claims arising under Texas consumer protection laws.

xiv. Washington

Plaintiffs' personal injury damage claims are barred under Washington's consumer protection laws. *See Ambach v. French*, 216 P.3d 405, 408 (Wash. 2009) ("Personal injury damages, however, 'are not compensable under the CPA' and do not constitute 'injury to business or property'"). Accordingly, it will be recommended that the Court grant Respironics's motion to dismiss Plaintiffs' claims arising under Washington's consumer protection law.

2. Jurisdictions Limiting Private Rights of Action for Damages

In support of its motion, Respironics asserts that the consumer protection statutes of Delaware, Georgia, Illinois, Maine, and Nebraska preclude recovery of damages. Supp. Br. (ECF No. 1346) at 48 and Table F(4). In response, Plaintiffs assert that dismissal is not warranted because each of the statutes permits actions for injunctive/equitable relief. Opp. Br. (ECF No. 1644) at 47. At oral argument,

Plaintiffs' counsel reiterated that Plaintiffs' claims arising under the state consumer protection acts should not be dismissed because the claims do not foreclose "relief of the injunctive/declaratory nature." Or. Arg. J. 10 (ECF No. 2129) at p. 155:4-7.

The Delaware, Georgia, Illinois, Maine, and Nebraska laws do allow for injunctive relief. However, Count XVI of the PIAC does not clearly support a claim for injunctive relief. In Count XVI, Plaintiffs allege only past harms and fail to allege a concrete risk of ongoing or future harm sufficient to allege a claim for injunctive relief. *See* PIAC (ECF No. 834) at ¶ 616 ("Plaintiffs were injured and suffered ascertainable losses of money or property by Philips' unlawful conduct."); ¶ 622 ("Plaintiffs relied upon Philips' misrepresentations and omissions in deciding to use the Recalled Devices.") In the absence of a showing of future harm, a court cannot award injunctive relief. *See U.S. v. W.T. Grant Co*., 345 U.S. 629, 633 (U.S. 1953) ("The purpose of an injunction is to prevent future harms."). *Anderson v. Davila*, 125 F.3d 148, 164 (3d Cir. 1997) (noting injunctive relief is only appropriate "where there exists a threat of irreparable harm such that legal remedies are rendered inadequate.");

In this case, Plaintiffs have not alleged a risk of future harm. All harm has already occurred and Plaintiffs do not allege such harms are ongoing. Nor do Plaintiffs assert that they are making these claims to prevent future, repetitive conduct by Respironics to prevent similarly situated individuals from suffering the

same harm. Absent an allegation of a threat of future harm, Plaintiffs cannot recover injunctive relief. Thus, Plaintiffs' sole relief under the consumer protection statutes of Delaware, Georgia, Illinois, Maine, and Nebraska, is foreclosed. Accordingly, it will be recommended that the Court grant Respironics's motion to dismiss Plaintiffs' claims arising under the consumer protection statutes of Delaware, Georgia, Illinois, Maine, and Nebraska.

3. Jurisdictions Requiring Privity

Respironics asserts that fourteen states and the District of Columbia limit private rights of action under their consumer protection statutes to only direct purchasers.[12] Supp. Br. (ECF No. 1346) at 48 and Citation Table F(6). Thus, Respironics asserts Plaintiffs' claims arising under these jurisdictions' laws must be dismissed for lack of privity because Plaintiffs purchased the Recalled Devices from DME sources and not from Philips. *Id*.

i. Alabama

The Alabama Deceptive Trade Practices Act, Ala. Code §8-19-1, does not specify a privity requirement. Plaintiffs point to Ala. Code §8-19-5 which "proscribes a variety of wrongdoing that naturally extends beyond [the] direct seller

[12] Because it has been recommended that the Court dismiss Plaintiffs' statutory consumer protection claims arising under the laws of Georgia, Idaho, Maine, Pennsylvania, New Mexico, and Tennessee law on other grounds presented by Respironics, the Court will review only the law of the nine remaining jurisdictions.

including '[e]ngaging in any other unconscionable, false, misleading, or deceptive act or practice in the conduct of trade or commerce.'" Opp. Br. (ECF No. 1644) at 67, Chart 14. Because there is no clear statutory language limiting actions under the statute to direct purchasers and Respironics had not cited any dispositive case law in support of its arguments, it will be recommended that the Court deny Respironics's motion to dismiss the claims asserted under the Alabama Deceptive Trade Practices Act.

ii. Arizona

In *Watts v. Medicis Pharm. Corp*., 365 P.3d 944, 953 (Ariz. 2016), the Arizona Supreme Court held that a plaintiff need not allege a "direct merchant-consumer transaction" to succeed on a statutory consumer fraud claim, but rather must show "a false promise or misrepresentation made in connection with the sale or advertisement of 'merchandise,'" including prescription pharmaceuticals. The case cited by Respironics, *Sullivan v. Pulte Home Corp*., 306 P.3d 1, 2 (Ariz. 2013), is distinguishable as it dealt with a claim for construction defects brought by a subsequent purchaser of a house. Supp. Br. (ECF No. 1346) at 69. Because the claim in *Watts* concerned a prescription product and a claim arising under the Consumer Fraud Act, it is clear that privity is not required here. Accordingly, it will

be recommended that the Court deny Respironics's motion to dismiss the Arizona Consumer Fraud Act claim for lack of privity.

iii. The District of Columbia

District of Columbia consumer protection law, D.C. Code §§28-3901, *et seq.*, defines "consumer" expansively to include anyone who "does or would purchase, lease or receive consumer goods." The statute also covers a broad range of activities affecting consumers. *See* D.C. Code § 28-3904. Because Respironics has not identified any case law interpreting the District of Columbia law to require a showing of privity, it will be recommended that the Court deny Respironics's motion to dismiss Plaintiffs' unfair or deceptive trade practices claim under the law of the District of Columbia.

iv. Kentucky

Skinner v. Ethicon, Inc., No. CV 19-472, 2021 WL 640809, at *4 (E.D. Ky. Feb. 18, 2021), recognized that the Kentucky Consumer Protection Act "plainly contemplates an action by a purchaser against his immediate seller." *See Neeley v. Wolters Kluwer Health, Inc.*, No. 4:11-CV-325 JAR, 2013 WL 3929059, at *17 (E.D. Mo. July 30, 2013) (no direct purchase requirement under KCPA). In *Naiser v. Unilever U.S., Inc.*, 975 F. Supp. 2d 727, 743 (W.D. Ky. 2013), however, the Court recognized an exception to the privity requirement where the defendant made express warranties for the plaintiffs' benefit. Under these circumstances, dismissal

of the Plaintiffs' claims under the Kentucky Consumer Protection Act at this stage of the case is premature. Accordingly, it will be recommended that the Court deny Respironics's motion to dismiss Plaintiffs' claims under the Kentucky Consumer Protection Act.

v. Mississippi

The Mississippi consumer protection act, Miss. Code Ann. §75-24-1, *et seq*., allows claims by plaintiffs who suffer ". . . any ascertainable loss of money or property, real or personal, as a result of the use or employment by the seller, lessor, manufacturer or producer" of a prohibited act. The statute thus reflects a broad interpretation of the class of plaintiffs who may bring claims and does not clearly require a showing of privity. Thus, it will be recommended that the Court deny Respironics's motion to dismiss Plaintiffs' claims under the Mississippi Consumer Protection Act.

vi. Missouri

In *Gibbons v. J. Nuckolls, Inc*., 216 S.W.3d 667, 670 n.13 (Mo. 2007), the Supreme Court of Missouri expressly declined to impose a privity requirement for a plaintiff to bring a claim under the Missouri Merchandise Merchandising Practices Act ("MMPA"). In light of this holding by Missouri's highest court, it will be recommended that the Court deny Respironics's motion to dismiss Plaintiffs' claims under the MMPA.

vii. Rhode Island

The plain text of the Rhode Island Unfair Trade Practices and Consumer Protection Act, 6 R.I. Gen. Laws Ann. § 6-13.1-11, does not require privity to bring an action. Further, the case on which Respironics relies, *R.I. Laborers' Health & Welfare Fund ex rel. Trustees v. Philip Morris, Inc*., 99 F. Supp. 2d 174, 189 (D.R.I. 1999), is plainly distinguishable as the Court did not address the issue of whether Rhode Island law required direct privity. Supp. Br. (ECF No. 1346) at 69. Accordingly, it will be recommended that the Court deny Respironics's motion to dismiss the Rhode Island Unfair Trade Practices and Consumer Protection Act claim.

viii. Vermont

The case of *Elkins v. Microsoft Corp*., 817 A.2d 9, 13 (Vt. 2002), is dispositive. There, the Supreme Court of Vermont assessed whether the Vermont Consumer Protection Act requires privity for a plaintiff to assert a claim. *Id*. The court recognized the protection of "the public against 'unfair or deceptive acts or practices' . . . underlies a private remedy section that allows suits by 'any consumer' with no suggestion of a distinction between direct and indirect purchasers." *Id.*

Accordingly, it will be recommended that the Court deny Respironics's motion to dismiss Plaintiffs' claims under the Vermont Consumer Protection Act.

ix. West Virginia

Both parties rely upon the text of the West Virginia Consumer Credit and Protection Act, codified at W. Va. Code Ann. §46A-6-106. The statute provides that "any person who purchases or leases good or services" and suffers an injury may bring an action. W. Va. Code Ann. §46A-6-106(a). The Act does not specify a privity requirement, and Respironics has not cited any dispositive case law on this issue. Accordingly, it will be recommended that the Court deny Respironics's motion to dismiss Plaintiffs' claims under the West Virginia Consumer Credit and Protection Act.

4. Jurisdictions Barring Claims for Consumer Protection Stemming from Medical Devices

In support of its motion, Respironics asserts twenty-three states and the District of Columbia limit consumer protection statutes to claims involving the purchase or lease of goods for personal, family or household uses. Supp. Br. (ECF No. 1346) at 48. Respironics asserts that medical devices like the Recalled Devices do not fall within such uses.[13] *Id*. In response, Plaintiffs assert that the Recalled

[13] The Court having dismissed Plaintiffs' consumer protection claims arising under the laws of Alaska, Georgia, Hawaii, Illinois, Iowa, Kentucky, Maine, New Mexico, Ohio, Oregon, Pennsylvania, Tennessee, Texas, and Washington on other

Devices are personal medical devices subject to these laws and distinguishable from implanted medical devices prior courts have recognized are not subject to these laws. Opp. Br. (ECF No. 1644) at 47. At oral argument, Plaintiffs' counsel highlighted several cases Plaintiffs rely on to assert that consumers' purchases of the Recalled Device and their daily use of the device distinguish the Recalled Devices from medical devices which prior courts have held to not be personal devices. Or. Arg. J. 10 (ECF No. 2129)156:1-159:25. When questioned by Judge Conti as to whether the consumer protection laws at issue with regard to the medical devices question are uniform laws to be interpreted in the same way, Plaintiffs' counsel agreed such an argument could be persuasive, but stressed there was insufficient case law from which to draw the conclusion that a medically-prescribed device is not a personal good. *Id*. at 175:9-176:19. With this background in mind, the Court will address each jurisdiction's laws in turn.

i. Alabama

In *Collins v. Davol, Inc*., 56 F. Supp. 3d 1222, 1232, n.9 (N.D. Ala. 2014), the court addressed the applicability of the Uniform Commercial Code's statute of limitations in the context of a surgically-implanted medical device. The court reasoned that a medical "device is clearly inconsistent with the definition of

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grounds presented by Respironics will not analyze Respironics's claims regarding the applicability of those jurisdictions' consumer protection acts to medical devices.

'consumer good' i.e., 'goods that are used or bought for use primarily for personal, family, or household purposes. *Id.* But the District Court did not address whether a medical device falls within the purview of Alabama's consumer protection act.

In response, Plaintiffs rely on Ala. Code §8-19-3(4) ("Consumer" is "[a]ny natural person who buys goods or services for personal, family, or household use") and Ala. Code §8-19-3(14) (trade or commerce includes any good or article without limitation) to assert there is no medical device limitation in the statute. Opp. Br. (ECF No. 1644) at 68. A review of the statute demonstrates there is no limitation in the statute that could be interpreted to limit claims regarding medical devices. In the absence of statutory text and case law supporting Respironics's argument, it will be recommended that the Court deny Respironics's motion to dismiss the Alabama Consumer Protection Act claim on the ground that it does not cover devices of the kind at issue here.

ii. California

Although Respironics views the text of California's Consumers Legal Remedies Act ("CLRA") as excluding medical devices, the text of the statute does not reflect such a limitation. *See* Cal. Civ. Code Ann. § 1761; Supp. Br. (ECF No. 1346) at 69. Plaintiffs rely on a number of cases recognizing that the consumer protection statutes should be broadly interpreted to "'protect consumers against unfair and deceptive trade practices and to provide efficient and economical

procedures to secure such protection.'" *Wang v. Massey Chevrolet*, 118 Cal. Rptr.2d 770, 778 (Cal. Ct. App. 2002) (citing *Hogya v. Superior Court*, 142 Cal. Rptr. 325 (1977). Opp. Br. (ECF No. 1644) at 38. Plaintiffs also cite persuasive case law demonstrating California courts have applied the CLRA in contexts similar to this one. *Id*. *See, e.g., In re Vioxx Class Cases*, 103 Cal. Rptr. 3d 83, 87-88 (Cal. Ct. App. 2009) (applying CLRA to pharmaceutical products); *Steroid Hormone Prod. Cases*, 104 Cal. Rptr. 3d 329 (Cal. App. 2d Dist. 2010) (applying CLRA to nutritional supplements). Thus, Respironics has not clearly demonstrated that the Recalled Devices would not be covered by the CLRA and it will be recommended that the Court deny Respironics's motion to dismiss the CLRA claims.

iii. District of Columbia

Respironics merely references District of Columbia Consumer Protection Procedure Act ("CCPA"), D.C. Code Ann. §§ 28-3901, *et seq*. Supp. Br. (ECF No. 1346) at 69; Repl. Br. (ECF No. 1827) at 49 (generally contesting Plaintiffs' case law as inapplicable). But that statute has a broad definition of goods that likely encompasses medical devices. *See* D.C. Code § 28-3901 (defining goods and services as "any and all parts of the economic output of society, at any stage or related or necessary point in the economic process, and includes consumer credit, franchises, business opportunities, real estate transactions, and consumer services of all types"). Further, courts have applied the CCPA to quasi-medical products and

prescription drugs, demonstrating courts have not adopted as narrow an interpretation of the CCPA as Respironics advocates for. *See, e.g., Ctr. of Inquiry Inc. v. Walmart, Inc*., 283 A.3d 109 (D.C. 2022) (applying CCPA to sale of homeopathic and over the counter drugs). Accordingly, it will be recommended that the Court deny Respironics's motion to dismiss the CCPA claim on this ground.

iv. Indiana

The Indiana Deceptive Consumer Sales Act defines a "consumer transaction" as "a sale, lease, assignment, award by chance, or other disposition of an item of personal property, real property, a service, or an intangible . . . that are primarily personal, familial, charitable, agricultural, or household, or a solicitation to supply any of these things." This provision has been interpreted to cover prescription drug sales. *See, e.g., In re Actiq Sales & Mktg. Practices Litig.*, 790 F.Supp.2d 313, 325-26 (E.D. Pa. 2011) (applying IDCA to prescription drug sales); *In re Bextra & Celebrex Mktg. Sales Practices & Prod. Liab. Litig*., 495 F. Supp. 2d 1027, 1036-37 (N.D. Cal. 2007) (allowing claims under IDCA for prescription drugs to continue in light of "dearth of Indiana law on this issue."). Under these circumstances it will be recommended that the Court deny Respironics's motion to dismiss the IDCA claim.

v. Louisiana

Respironics challenges the applicability of the Louisiana Unfair Trade Practices and Consumer Protection Law by referencing its definition of "consumer

transaction" as "any transaction involving trade or commerce to a natural person, the subject of which transaction is primarily intended for personal, family, or household use." Supp. Br. (ECF No. 1346) at 69 (citing La. Stat. Ann. § 51:1402(3)). Plaintiffs rely on several portions of the statute to show that the statute has a broad reach. Opp. Br. (ECF No. 1644) at 69 (citing La. Stat. Ann. §51:1405 ("Unfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce are hereby declared unlawful."); La. Stat. Ann. §51:1409(A) ("Any person who suffers any ascertainable loss of money ... as a result of ... an unfair or deceptive method, act, or practice declared unlawful by R.S. 51:1405, may bring an action")). Respironics has failed to show that its Devices are not covered by the Louisiana Unfair Trade Practices and Consumer Protection Law. Accordingly, it will be recommended that the Court deny Respironics's motion to dismiss the claim under the Louisiana Unfair Trade Practices and Consumer Protection Law.

vi. Maryland

In *Pease v. Abbott Laboratories, Inc.*, No. CIV. JKB-12-1844, 2013 WL 174478, at *2 (D. Md. Jan. 16, 2013), the court ruled that the Maryland Consumer Protection Act was "inapplicable to Abbott's sale of prescription drugs because prescription drugs are not 'consumer goods' under the MCPA." However, in *Mayor and City Council of Baltimore v. GlaxoSmithKline, LLC*, No. 24-C-20-004788, 2022 WL 537004, at *6 (Md. Cir. Ct. Jan. 28, 2022), the court allowed a claim asserted

under the Maryland Consumer Protection Act to proceed. Under these circumstances it will be recommended that Respironics's motion to dismiss the claim under the Maryland Consumer Protection Act be denied.

vii. Michigan

Michigan Consumer Protection Act (MCPA), MCL 445.901, *et seq*., does not clearly exempt medical devices. It provides that a covered transaction under the statute includes "the conduct of a business providing goods, property, or service primarily for personal, family, or household purposes." *Id.,* § 445.902(g). *In re Bextra & Celebrex Mktg. Sales Practices & Prod. Liab. Litig*., however, offers helpful analysis of this question. 495 F.Supp.2d 1027, 1032-34 (N.D. Cal. 2007) (purchase of drugs "were primarily for personal purposes, that is, the personal use of the patients."). There, in interpreting Michigan law, the court held that the plaintiffs' use of prescription drugs was for personal purposes under the MCPA. Thus, it appears that courts interpreting the MCPA have adopted a broader definition of personal use than advocated by Respironics. Under these circumstances it will be recommended that the Court deny Respironics's motion to dismiss the claim under the Michigan Consumer Protection Act.

viii. Mississippi

Mississippi Consumer Protection Regulations do not explicitly exempt medical devices and Respironics does not provide additional support for its

assertions that such devices are exempt. Supp. Br. (ECF No. 1346) at 70) (citing Miss. Code § 75-24-15 (covering ". . . any person who purchases or leases goods or services primarily for personal, family or household purposes")). In response, Plaintiffs rely on several sections of the Mississippi Consumer Protection Regulations. Opp. Br. (ECF No. 1644) at 70 (citing Miss. Code Ann. §75-24-15(1) ("any person who purchases or leases goods or services primarily for personal, family or household purposes"); Miss. Code Ann. §75-24-3(b) ("'Trade' and 'commerce' mean the advertising, offering for sale, or distribution of any services and any property, tangible or intangible, real, personal or mixed, and any other article, commodity, or thing of value wherever situated ... and any trade or commerce directly or indirectly affecting the people of this state")). In the absence of clear statutory language exempting medical devices and case law interpreting the MCPR to exempt medical devices, it will be recommended that the deny Respironics's motion to dismiss the claims under the Mississippi Consumer Protection Regulations.

ix. Missouri

The Missouri Merchandising Practices Act does not clearly exempt medical devices and Respironics does not offer dispositive case law to support its arguments. See Supp. Br. (ECF No. 1346) at 70; Reply Br. (ECF No. 1827) at 49. Courts have concluded that prescription drugs are covered by the statute as merchandise. *See*,

e.g., *Plubell v. Merck & Co., Inc*., 289 S.W.3d 707 (Mo. Ct. App. 2009) (assessing class action claim for defect in prescription drug under MMPA); *see also Polk v. KV Pharmaceutical Co*., No. 4:09-CV-00588 SNLJ, 2011 WL 6257466 at *5 (E.D. Mo. Dec. 15, 2011) (noting prescription drug was merchandise purchased for personal use under MMPA). Accordingly, it will be recommended that the Court deny Respironics's motion to dismiss Plaintiffs' claims arising under the Missouri Merchandising Practices Act.

x. Montana

The Montana Consumer Protection Act does not clearly exempt medical devices, see Mont. Code Ann. §30-14-102 (recognizing coverage for "goods, services, real property or information"); §30-14-102(1) ("'Consumer' means a person who purchases or leases goods . . . primarily for personal, family, or household purposes."). *See generally Vinion v. Amgen, Inc*., 2004 WL 6057351, at *4 (D. Mont. Aug. 30, 2004) (court rejected drug study participants' MCPA claims but suggested claims would lie if drugs were purchased "primarily for personal purposes" instead of "for the benefit of the study"). In the absence of clear authority indicating the Recalled Devices would be exempt, it will be recommended that the

Court deny Respironics's motion to dismiss Montana Consumer Protection Act claim.

xi. Rhode Island

The Rhode Island Deceptive Trade Practices Act ("DPTA") does not clearly address medical devices. *See* R.I. Gen. Laws §6-13-1-5.2(a)). It is, however, a remedial act that is to be construed liberally. *See Long v. Dell, Inc*., 93 A.3d 988, 1000 (R.I. 2014). Under these circumstances it will be recommended that the Court deny Respironics's motion to dismiss Plaintiffs' claims arising under the DTPA.

xii. Vermont

The Vermont Unfair Trade Practices statute is codified at Vt. Stat. Ann. tit. 9, § 2451 *et seq*. The statute does not clearly exempt medical devices. Instead, the statute provides a wide-ranging definition of goods covered under the statute, including "any objects, wares, goods, commodities, work, labor, intangibles, course of instruction or training, securities, bonds, debentures, stocks, real estate, or other property or services of any kind." *Id*. at §2451a(2). The case upon which Respironics relies, *Otis-Wisher v. Medtronic, Inc.*, 616 Fed. App'x. 433, 435 (2d Cir. 2015), is factually distinguishable as the plaintiff there was treated with a product during a spinal surgery which she did not purchase. Supp. Br. (ECF No. 1346) at 70. Thus, Respironics has not demonstrated that the Recalled Devices would be exempt from the Rhode Island consumer protection statute and it will be

recommended that the Court deny Respironics's motion to dismiss the consumer protection claim.

xiii. Virginia

The case Respironics cites in support of its argument that the Virginia Consumer Protection Act exempts medical devices does not address concern medical devices, but instead concerns a water heater. Supp. Br. (ECF No. 1346) at 70 (citing *Liu v. Lowe's Home Improvement*, No. 3:20-CV-00056, 2022 WL 528863, at *1 (W.D. Va. Feb. 22, 2022) ("This case is about a hot water heater installation that went awry.")) Further, the discussion of the Virginia legislation merely cites the elements of a claim under the Act and does not address any exceptions or exemptions. *Id*. In *Com. Ex rel. Herring v. Teva Pharm. USA, Inc*., however, No. CL19-5566, 2020 WL 12991889 (Va. Cir. Ct. Nov. 13, 2020), however, the court found that defendants' acts of advertising and selling their prescription drugs for resale are covered by the Act. There, the court recognized that sales of the prescription drugs Actiq and Fentora would be transactions subject to the VCPA. *Id*. at *3. This opinion more closely addresses the question of whether the Recalled

Devices would be subject to the VCPA. Accordingly, it will be recommended that the Court deny Respironics's motion to dismiss the claim under the VCPA.

xiv. West Virginia

The case Respironics cites, *White v. Wyeth*, 705 S.E.2d 828, 838 (W. Va 2010), recognizes that prescription drugs do not fall within the types of products intended to be covered by the West Virginia Consumer Protection Act. Supp. Br. (ECF No. 1346) at 70 ("Prescription drug cases are not the type of private causes of action contemplated under the terms and purposes of the WVCPA because the consumer cannot and does not decide what product to purchase. Accordingly, for the reasons stated above, we find that the private cause of action afforded consumers under West Virginia Code § 46A–6–106(a) does not extend to prescription drug purchases."). *White*, however, has been limited to cases where a physician made the choice. *See West Virginia ex rel. McGraw v. Bristol Myers Squibb Co*., No. 13-1603 (FLW), 2014 WL 793569 at *6 (D.N.J. Feb. 26, 2014) (limiting application *White* to private causes of action where doctor's medical judgment determines a consumer's prescription medication).

At this stage of the case, it cannot be determined whether doctors or individual plaintiffs chose the Philips Devices. Accordingly, it will be recommended that the

Court deny Respironics's motion to dismiss the claim under the West Virginia Consumer Protection Act.

xv. Wyoming

Both parties rely on the Wyoming Consumer Protection Act in support of their arguments. Supp. Br. (ECF No. 1346) at 70; Opp. Br. (ECF No. 1644) at 71. However, the statute does not address the question before the Court. The statute defines a "consumer transaction" subject to the statute as "the advertising, offering for sale, sale or distribution or any merchandise to an individual for purposes that are primarily personal, family or household." Wyo. Stat. Ann. §40-12-102(a)(ii). Further, the statute contains a broad definition of merchandise subject to the act, including "any service or any property, tangible or intangible, real, personal or mixed, or any other object, ware, good, commodity, or article of value wherever situated." Wyo. Stat. Ann. §40-12-102(a)(vi). In the absence of case law discussing the question of whether medical devices are exempt from the Wyoming Consumer

Protection Act, it will be recommended that the Court deny Respironics's motion to dismiss the claims under the Wyoming Consumer Protection Act.

5. Jurisdictions Precluding Claims in Areas Subject to Regulatory Oversight

Respironics asserts Plaintiffs' consumer protection claims fail in a number of jurisdictions where the governing law excludes claims subject to regulatory oversight. Supp. Br. (ECF No. 1346) at 46.[14]

i. Colorado

Respironics asserts that the provision in Colorado Consumer Protection Act that it does not apply to "[c]onduct in compliance with the orders or rules of, or a statute administered by, a federal, state, or local governmental agency," Colo. Rev. Stat. Ann. §6-1-106(1), precludes claims under the Colorado statute. Supp. Br. (ECF No. 1346) at 67. However, as explained in *Shostrom v. Ethicon, Inc.*, No. 20-CV-1933-WJM-STV, 2021 WL 778994 at *9–10 (D. Colo. Mar. 1, 2021):

> Shostrom argues that the CCPA only bars claims in compliance with the statute administered by a government agency—here, the FDA. (ECF No. 44 at 16– 17.) Shostrom relies on *Showpiece Homes Corp. v. Assurance Co. of Am.*, 38 P.3d 47, 56 (Colo. 2001), as modified on denial of reh'g (Jan. 11, 2002), in which the Colorado Supreme Court held "that section 6–1–106(1)(a) exempts

[14] Having recommended that the Court dismiss Plaintiffs' consumer protection claims arising under the laws of Alaska, Georgia, Hawaii, Illinois, Iowa, Kentucky, Maine, New Mexico, Ohio, Oregon, Pennsylvania, Tennessee, Texas, and Washington on other grounds presented by Respironics, there is no need to assess Respironics's additional arguments for dismissal of consumer protection claims in those states.

> only those actions that are 'in compliance' with other laws." The court explained that conduct amounting to deceptive or unfair trade practices, however, would not appear to be "in compliance" with other laws. *Id.* Reasoning that the mere existence of a regulatory body to oversee certain standards of an industry (there, the insurance industry) does not remove all acts and practices of that industry from the provisions of the CCPA, the court found that the General Assembly could not have intended to exclude from the protection of the CCPA the large number of industries that are subject to regulation. *Id.* at 56–57.
>
> In the Court's view, while Showpiece Homes concerns the insurance industry and does not discuss medical devices or the FDA, the reasoning and ultimate conclusion of the Colorado Supreme Court in that case is dispositive here. Shostrom has asserted that Ethicon's "false and misleading representations to the public were not in compliance with any federal law," and as such, the exception does not bar the CCPA claim.

The reasoning in *Shostrom* is persuasive. Accordingly, it will be recommended that the Court deny Respironics' motion to dismiss the claims under the CCPA.

ii. Connecticut

The Connecticut Unfair Trade Practices Act similarly does not apply to "[t]transactions or other actions otherwise permitted under law as administered by any regulatory board or officer acting under statutory authority of the state or of the United States." Conn. Gen. Stat. Ann. §42-110c(a)(1). The analysis in *Shostrom* is applicable here. Accordingly, it will be recommended that the Court deny

Respironics's motion to dismiss the claims under the Connecticut Unfair Trade Practices Act.

iii. Massachusetts

The Massachusetts consumer protection laws do not apply to "transactions or actions otherwise permitted under laws as administered by any regulatory board of officer acting under statutory authority of the commonwealth or of the United States." Mass. Gen. L. Ch. 93A §3. Relying on *Com. v. Fremont Inv. & Loan*, Plaintiffs assert this exception applies only where a regulatory scheme "affirmatively permits the practice which is alleged to be unfair or deceptive." Opp. Br. (ECF No. 1644) at 63; 897 N.E.2d 548, 561 (Mass. 2008) (quoting *Fleming v. Nat'l Union Fire Ins. Co*., 837 N.E.2d 1113, 1121 (Mass. 2005)). As there is no indication here that Massachusetts affirmatively permitted the challenged conduct here, it will be recommended that the Court deny Respironics's motion to dismiss Plaintiffs' claims under the Massachusetts consumer protection law.

iv. Michigan

Michigan Consumer Protection Act also provides that "[t]his act does not apply to . . . [a] transaction or conduct specifically authorized under laws administered by a regulatory board or officer acting under statutory authority of this state or the United States." Plaintiffs rely on the opinion of the District Court for the Eastern District of Michigan in *Robertson v. State Farm Fire & Cas. Co*. 890 F. Supp

671, 676 (E.D. Mich. 1995), in which the court explained that "the inquiry under §1(a) is not whether the conduct is subject to regulation, but rather whether the conduct is 'specifically authorized," and merely being subject to "regulation by a board or agency is insufficient to invoke §1(a)'s exemption." *Id*.; Opp. Br. (ECF No. 1644) at 64. Accordingly, it will be recommended that the Court deny Respironics's motion to dismiss Plaintiffs' claims under the Michigan Consumer Protection Act.

v. Oklahoma

The Oklahoma Consumer Protection Act exempts "[a]ctions or transactions regulated under laws administered by the Corporation Commission or any other regulatory body or officer acting under statutory authority of this state or the United States." 15 Okla. Stat. §754(2). "The OCPA was enacted to protect consumers from unfair and deceptive trade practices." *Money v. Bristol-Myers Squibb Co*., No. CIVA 307CV-1100 FLW, 2009 WL 5216987 at *6 (D.N.J. Dec. 30, 2009). Plaintiffs' reliance on *Money* is persuasive. The statutory exemption was not "applicable merely because the promotion and marketing of prescription drugs are generally regulated." 2009 WL 5216987 at *6. Accordingly, it will be recommended that the Court deny Respironics's motion to dismiss the claim under the Oklahoma Consumer Protection Act.

vi. Rhode Island

The Rhode Island Deceptive Trade Practices Act exempts from its provisions "actions or transactions permitted under laws as administered by the department of business regulation or other regulatory body or officer acting under statutory authority of this state or the United States." 6 Rhode Island General Laws § 6-13.1-4(a). The exemption has been applied in the context of vaccines. *See Balasco v. Merck & Co., Inc.*, No. 1:20-CV-0364-MSM-PAS, 2021 WL 8443734 at *1 (D.R.I. Apr. 22, 2021). Here, by way of contrast, no showing has been made that the FDA approved the Recalled Devices with the PER-PUR foam. Accordingly, it will be recommended that the Court deny the motion to dismiss the claim under Rhode Island's Deceptive Trade Practices Act.

4. Jurisdictions Requiring Allegations of Causation

Respironics asserts thirty-seven states require factual pleading of causation and/or reliance to state a viable consumer protection claim, and that Plaintiffs have failed to allege either element. Supp. Br. (ECF No. 1346) at 46-47. As reflected in their Citation Table, Plaintiffs appear to concede that allegations of causation are required under a number of jurisdictions' laws. Opp. Br. (ECF No. 1644) at 65. In the context of a master complaint, however, it is not surprising that allegations satisfying the elements of reliance and causation have not been made. Satisfaction of those requirements is best assessed on a plaintiff-by-plaintiff basis and challenges

should be made in the context of short form complaints or at the bellwether stage. The PIAC has plead sufficient facts to make it at least plausible that Plaintiffs in each of the at-issue states relied upon alleged misrepresentations. A state-by-state exposition of the law on reliance and causation could be undertaken, but it would be advisory only because it would not assess any particular plaintiff's circumstances. Accordingly, it will be recommended that consideration of the question of whether a particular plaintiff can satisfy the reliance and causation requirements of a claim under a state's consumer protection law be deferred.

5. Jurisdictions Requiring Evidence of Scienter

In support of its motion to dismiss, Respironics asserts Plaintiffs have failed to allege scienter with specificity as required by the laws of nineteen jurisdictions. Supp. Br. (ECF No. 1346) at 47. Plaintiffs appear to concede that a number of jurisdictions do require scienter, as evidenced by its citation tables in support of its opposition.[15] Opp. Br. (ECF No. 1644) at 65. There is no need to conduct a state-by-state analysis, however, as the PIAC adequately alleged Philips' knowledge of the existence of the defective condition of its breathing assistive devices and failed to disclose that knowledge. Whether Plaintiffs from a specific state can prove scienter is, of course, a separate issue that is not properly presented at this stage of

[15] As the Court will provide Plaintiffs leave to amend their consumer fraud claims, the Court will analyze Respironics's arguments under these jurisdictions.

the case. Accordingly, it will be recommended that the Court deny Respironics's challenge to the state consumer protection act claims for failure to allege scienter without prejudice, of course, to the issue being presented by way of a summary judgment motion or at the bellwether stage.

6. Jurisdictions Barring Claims for Consumer Protection Involving Out of State Conduct

Respironics asserts that twenty jurisdictions and the District of Columbia require the conduct at issue in a consumer protection claim occur within the state, and that Plaintiffs' claims fail to allege conduct occurring within each jurisdiction. Supp. Br. (ECF No. 1346) at 49. The PIAC, however, alleges:

> Philips marketed and advertised the Recalled Devices to consumers, physicians, and other healthcare entities in *each jurisdiction*. In addition, *in those jurisdictions, Philips sold the Recalled Devices, shipped Recalled Devices, and otherwise engaged in trade or commerce, or conducted business, related to the Recalled Devices*.

PIAC (ECF No. 834) at ¶ 610 (emphasis added). This allegation is sufficient in the context of a master complaint to satisfy the "in state" conduct requirement of state consumer protection laws so as to preclude dismissal of those claims. Accordingly, it will be recommended that the Court deny Respironics's motion to dismiss the state consumer protection claims for failure to allege in-state conduct.

7. Jurisdictions Requiring Pre-Suit Notice

Respironics has challenged Plaintiffs' consumer protection act claims arising under the laws of Alabama, Alaska, California, Georgia, Indiana, Maine, Massachusetts, Texas, Utah, West Virginia, and Wyoming for lack of pre-suit notice. Supp. Br. (ECF No. 1346) at 49. Respironics also raised the question of pre-suit notice with respect to Plaintiffs' warranty claims. *Id*. at 36-37. Respironics's argument regarding pre-suit notice concerns the sufficiency of the notice. Plaintiffs allege that Defendants were put on notice of the alleged defects and possibility of litigation by virtue of two letters sent to Philips by Plaintiffs on September 8, 2021, and May 16, 2022. PIAC (ECF No. 834) at ¶ 506. Respironics contends that these letters were not sufficient to provide the requisite pre-suit notice because they were not timely and did not abide by procedural requirements. In other words, Respironics challenges the sufficiency of these letters rather than the question of their existence. Respironics's challenge to the sufficiency of the pre-suit notice presents an issue of fact. *See Holtec International v. ARC Machines, Inc*., 492 F.Supp.3d 430, 444 (W.D. Pa. 2020). Accordingly, it will be recommended that Respironics's motion to dismiss the consumer protection act claims under the laws of Alabama, Alaska, California, Georgia, Indiana, Maine, Massachusetts, Texas,

Utah, West Virginia, and Wyoming for lack of pre-suit notice be denied. Respironics may reassert this argument following discovery.

D. UNJUST ENRICHMENT

Respironics moves this Court to dismiss Plaintiffs' unjust enrichment claims. In its Memorandum of Law in Support of its motion, Respironics cites the Restatement (Third) of Restitution and Unjust Enrichment § 1. Supp. Br. (ECF No. 1346) at 50 ("A person who is unjustly enriched at the expense of another is subject to liability in restitution."). Respironics refers back to its memorandum of law in support of its motion to dismiss the Third Amended Economic Loss Complaint for its unjust enrichment argument. *Id*.

In response, Plaintiffs assert they have pled a prima facie case of unjust enrichment under Restatement (First) of Restitution § 1 by asserting that Plaintiffs conferred a benefit on Respironics by using devices that were purchased on their behalf, that Respironics concealed a defect in the devices, and was unjustly enriched by its conduct. Opp. Br. (ECF No. 1643) at 49. Further, Plaintiffs assert that Philips can point to no case law supporting its assertion that the doctrine has no place in a personal injury claim.

The following analysis of a claim for unjust enrichment in the medical device context is persuasive:

> Defendants . . . argue that Plaintiff's unjust enrichment claim should be dismissed because Plaintiff received and used the TVT product

purchased from Defendants and, therefore, they were not unjustly enriched. "In products liability cases, courts in this Circuit applying Pennsylvania law dismiss unjust enrichment claims where the plaintiff received and used the product at issue." *Drumheller*, 2021 WL 1853407, at *17; *see also McGrain*, 2021 WL 3288601, at *12 ("Courts in this circuit have dismissed unjust enrichment claims in products liability actions where plaintiffs in fact received and used the product they purchased.") (citing *Mazur v. Milo's Kitchen, LLC*, 2013 WL 3245203, at *10 (W.D. Pa. June 25, 2013)). The *Drumheller* court granted Defendants' motion to dismiss the unjust enrichment claim in that case because the plaintiff "d[id] not allege she paid for but did not receive the product at issue; rather she allege[d] her dissatisfaction with the product." 2021 WL 1853407, at *18. Similarly, the *McGrain* court granted a motion to dismiss the plaintiff's unjust enrichment claim arising from the IVC filter that had been implanted in the plaintiff's abdomen, concluding that "[b]ecause Plaintiff acknowledges that she received and used Defendants' product, she cannot plausibly state a claim for unjust enrichment." *McGrain*, 2021 WL 3288601, at *12. More recently, the court granted a motion to dismiss an unjust enrichment claim in a products liability action arising from the implantation of a pelvic mesh device in *Brown v. C.R. Bard, Inc*., Civ. A. No. 21-1552, 2022 WL 420914 (E.D. Pa. Feb. 11, 2022). The *Brown* court noted that unjust enrichment claims have been dismissed "'in products liability actions where plaintiffs in fact received and used the product they purchased.'" *Id*. at *12 (quoting *McGrain*, 2021 WL 3288601, at *12). The *Brown* court explained that Courts have "reason[ed] that where a plaintiff acknowledges that she received and used the defendants product, the defendant cannot be found to have refused to provide such product." *Id*. (citing *McGrain*, 2021 WL 3288601, at *12). The *Brown* court dismissed the plaintiff's unjust enrichment claim with prejudice because "[she] was implanted with the [pelvic mesh device] in October 2010, where it remained for more than six years before being removed in December 2016" and the plaintiff "therefore cannot show that [the defendant] refused to provide a service or product and any amendment would be futile." *Id*. (citing *McGrain*, 2021 WL 3288601, at *12).

Here, the Complaint alleges that Plaintiff was implanted with the TVT product in 2011. Thus, accepting the Complaint's

> allegations as true, Plaintiff cannot plausibly allege that Defendants refused to provide her with a service or product in exchange for her payment. *See Brown*, 2022 WL 420914, at *12. We therefore grant the Motion to Dismiss as to Plaintiff's claim for unjust enrichment in Count XIII of the Complaint. We further conclude that any amendment of Count XIII would be futile, so we grant the Motion to Dismiss as to Count XIII with prejudice.

Bostic v. Ethicon Inc., No. CV 20-6533, 2022 WL 952129, at *16 (E.D. Pa. Mar. 29, 2022). *See also Tatum v. Takeda Pharm. North America, Inc*., No. 12-1114, 2012 WL 5182895, at *5 (E.D. Pa. Oct.19, 2012) (finding that the plaintiff's claim that the defendants were aware of the risks of the drug but chose not to disclose them failed to state a claim for unjust enrichment because there was no allegation that the defendants "refused to provide a service or goods after [plaintiffs] provided defendants with a benefit"); *In re Avandia Mktg., Sales Practices and Prod. Liab. Litig*., MDL No. 1871, 2011 WL 4007908, at * 2 (E.D. Pa. Sept.7, 2011) (finding that the plaintiff's allegations that the product at issue was not safe, that defendant knew it was not safe and promoted it anyway, failed to state a claim for unjust enrichment where the plaintiff received the product for which he paid); *Zafarana v. Pfizer, Inc*., 724 F.Supp.2d 545, 561 (E.D.Pa.2010) (the allegation that the defendants misled the plaintiffs into desiring a product, which the defendants then provided to the plaintiffs in exchange for payment, did not create quasi-contract liability).

Finding this precedent compelling and recognizing the incongruity of a claim for unjust enrichment in the context of a personal injury action, it will be recommended that the Court dismiss, with prejudice, Plaintiffs' claim for unjust enrichment.

E. PLAINTIFFS' MEDICAL MONITORING CLAIMS

As the parties note, determination of whether Plaintiffs have stated a claim for medical monitoring is a complex determination that requires more substantial briefing on the issue than the parties have offered in relation to the PIAC. Accordingly, the Court refers the parties to its analysis of medical monitoring claims contained in its Report and Recommendation on the Second Amended Class Action Complaint for Medical Monitoring.

With regard to Respironics's motion to dismiss Plaintiffs' medical monitoring claims contained in the PIAC, the Court finds Respironics's arguments unconvincing. In support of this motion, Respironics merely refers back to its Citation Table A in support of its motion to dismiss the Second Amended Class Action Complaint for Medical Monitoring ("MMSAC"). Supp. Br. (ECF No. 1346) at 52; Supp. Br. (MMSAC) (ECF No. 1352) at 40. A review of the cases provided in the table reveals that these cases focus on whether jurisdictions require evidence of a present physical injury to demonstrate a claim for medical monitoring, rather

than addressing whether the jurisdictions recognize independent claims for medical monitoring. Supp. Br. (MMSAC) (ECF No. 1352) at 40.

Thus, relying on the analysis contained in the Court's Report and Recommendation Regarding the Second Amended Class Action Complaint for Medical Monitoring it is recommended the Court deny Respironics's motion to dismiss claims arising under the following jurisdictions: Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, Georgia, Hawaii, Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Michigan, Minnesota, Mississippi, Missouri, Nebraska, Nevada, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Puerto Rico, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Virginia, Washington, Wisconsin, and Wyoming and grant Respironics's motion to dismiss claims arising under the laws of Montana and New Hampshire.

F. PLAINTIFFS' LOSS OF CONSORTIUM AND SURVIVORSHIP AND WRONGFUL DEATH CLAIMS

Although Respironics seeks the dismissal of Plaintiffs' claims for loss of consortium, survivorship, and wrongful death, Respironics does not offer analysis

or support for this argument. (ECF No. 1345 at 11). *Id*. Accordingly, it will be recommended that the motion be denied.

V. GROUP FOUR ISSUES

The parties placed in Group 4 for purposes of presenting oral argument on Respironics's motion to dismiss Plaintiffs' breach of express and implied warranty claims, negligent manufacturing, strict liability design defect, strict liability manufacturing defect, and battery claims.[16]

Respironics asserts that Plaintiffs' warranty claims are barred under the laws of several jurisdictions for lack of timeliness and a lack of privity. Supp. Br. (ECF No. 1346) at 35. Respironics also asserts Plaintiffs may not recover under their breach of express warranty claims because the design defect Plaintiffs allege is not included in the materials and workmanship warranty provided with the Recalled Devices. *Id*. at 32. [17]

[16] The Court having dismissed Plaintiffs' independent claim for punitive damages during oral argument, this report and recommendation does not address Respironics' argument regarding Count XXI of the Personal Injury Amended Complaint. PIAC at Count XXI; Or. Arg. J. 11 (ECF No. 2130) 54-55. As the parties have reached a settlement agreement as to the claims in the Third Amended Class Action Complaint for Economic Losses (ECF No. 785), this Report and Recommendation will not address the claims in that complaint that do not overlap with claims in the PIAC.

[17] Respironics asserts similar requests for dismissal of similar claims asserted in the Second Amended Medical Monitoring Claim ("MMSAC") in its Motion to Dismiss the Consolidated Second Amended Class Action Complaint for Medical Monitoring for Failure to State a Claim. (ECF No. 1351.) As these claims are

As to Plaintiffs' strict liability claims, Respironics argues Plaintiffs' strict liability design defect claims are repetitive of Plaintiffs' strict liability manufacturing defect claims and are barred under the laws of specific jurisdictions. Supp. Br. (ECF No. 1346) at 37.[18] Respironics asserts that Plaintiffs' strict liability manufacturing defect claims relate solely to the Trilogy Evo Ventilator, a device not at issue in this MDL. (ECF No. 1346) at 40. Finally, as to Plaintiffs' battery claims, Respironics asserts Plaintiffs have alleged only generalized harm and are otherwise unable to demonstrate Respironics intended to cause Plaintiffs bodily harm, requiring that this claim be dismissed. *Id.* at 50.

A. BREACH OF WARRANTY

1. Timeliness

Respironics moves to dismiss Plaintiffs' claims for breach of express and implied warranties because Plaintiffs' claims fall outside of the imputed two-year warranty period.[19] To assert a claim under the limited warranty, Respironics notes

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substantially similar, this Report and Recommendation will address these overlapping claims collectively.

[18] Respironics asserts the jurisdictions of Delaware, North Carolina, and Virginia bar strict liability claims encompassing both manufacturing and design defects. Respironics also asserts that California, the District of Columbia, Indiana, Iowa, Maryland, Massachusetts, Montana, New Mexico, New York, Ohio, Pennsylvania, South Dakota, Tennessee, Texas, and Wyoming have not adopted comment k of the Restatement (Second) of Torts on which Plaintiffs rely on. (ECF No. 1346 at 37).

[19] Respironics specifically requests dismissal of Plaintiffs' implied warranty claims arising under the laws of Alabama, Arizona, Arkansas, California, Colorado,

that Plaintiffs would "need to allege that a defect manifested in their particular devices within the two-year limited warranty period, and that Respironics was timely notified of the defect." Supp. Br. (ECF No. 1346) at 33, n. 16. Respironics asserts that Plaintiffs' "failure to allege both manifestation of the defect and notice to Respironics within the two-year warranty period" requires dismissal of claims arising in the jurisdictions listed in footnote 20. Supp. Br. (ECF No. 1346) at 35; PIAC (ECF No. 834) Ex. 47 at 32.

In response, Plaintiffs assert that they sufficiently alleged that the Recalled Devices suffered from a design defect that manifested in each Plaintiff's Device within the two-year warranty period because "each Device was made with the PE-PUR foam." Opp. Br. (ECF No. 1644) at 34. Plaintiffs likewise assert that enforcement of the two-year warranty period would be unconscionable because Respironics knew the devices were prescription breathing devices intended to assist individuals with breathing problems and knew that the Devices contained PE-PUR foam that presented a risk of off-gassing and degradation. *Id*.; *Carlson v. General Motors Corp*., 883 F.2d 287, 296 (4th Cir. 1989). Relying on *Winkworth v. Spectrum Brands, Inc*., Plaintiffs argue the Court should defer determination of this issue until

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Delaware, Florida, Georgia, Illinois, Indiana, Kentucky, Louisiana, Massachusetts, Michigan, Minnesota, Missouri, Montana, New Jersey, North Carolina, Ohio, Oklahoma, Pennsylvania, South Carolina, Tennessee, Texas, Vermont, Virginia, Washington, West Virginia, and Wisconsin.

after discovery. *Id*. at 35; No. 19-1011, 2020 WL 3574687 at *4-5 (W.D. Pa. June 30, 2020).

The parties' arguments regarding the nature of the defect inherently overlap with their arguments regarding the timeliness of Plaintiffs' warranty claims. Respironics asserts that Plaintiffs merely allege the Recalled Devices suffered from a design defect not covered by the warranty because a defect resulting from a "'manufacturer's choice to use a certain material to construct a product is a 'design decision,' and not a defect in 'materials and workmanship.'" Supp. Br. (ECF No. 1346) at 20 (citing *Davidson v. Apple, Inc.*, No. 16-CV-04942-LHK, 2017 WL 976048 at *11 (N.D. Cal. Mar. 14, 2017). Plaintiffs advocate for a broader interpretation of the alleged defect and assert that the inclusion of the term "product specifications" in the warranty should be construed to allow the alleged defect to allow coverage under the express warranty. Opp. Br. (ECF No. 1644) at 33.

If Plaintiffs are correct and the defect was a manufacturing and workmanship defect, that type of defect would likely have been present at the moment plaintiffs purchased the devices. If, however, the defect is a design defect, as Respironics asserts, the defect would likely manifest upon use. Thus, a determination of the applicability of the warranty and the timeliness of Plaintiffs' claims depends upon the determination of the type of defect at issue.

Where the distinction in the asserted types of defects is "a matter of semantics and sufficient facts are alleged to assert both," the determination of the type of defect cannot be made at the pleadings stage. *Winkworth,* 2020 WL 3574687, at *4 (citing *Alin v. American Honda Motor Co., Inc*., No. 08-4825, 2010 WL 1372308, at *6 (D.N.J. March 31, 2010)). Other District Courts within this Circuit have adopted similar approaches to determining the nature of a defect and denied motions to dismiss where resolution of the issues depended upon a determination of the nature of the defect. *See Davis v. BMW of North America, LLC*, No. 19-cv-19650, 2022 WL 3646571, at *4 ("[I]t is premature at this stage to dismiss Plaintiffs' express warranty claim on the grounds that is based on defective design as opposed to defects in material or workmanship" (quoting *In re Caterpillar, Inc*., *C13 & C15 Engine Prod. Liab. Litig*., No. 14-3722, 2015 WL 4591236, at *19 (D.N.J. July 29, 2015)); *Burnside v. Peterbilt Motors Company*, No. 3:17-CV-2121, 2019 WL 1427543 at *5 (M.D. Pa. March 29, 2019) (denying motion to dismiss for failure to plead specific defect because detailed theory of the nature of the defect "can and will be defined upon factual and expert discovery.").

When presented with a substantially similar circumstance in *Rice v. Electrolux Home Products, Inc*., the Middle District of Pennsylvania recognized that when a defect may be either a design defect or a manufacturing defect, "[d]iscovery is necessary to determine whether the defects in the [product] go beyond a design

defect and enter the ambit of a defect in materials." No. 4:15-CV-00371, 2015 WL 4545520 at *6-7 (M.D. Pa. July 28, 2015). There, in a case involving a defective microwave handle that would burn users, the court recognized that additional discovery was required to resolve the dispute as to what caused the alleged defect and whether the defendant "designed the handle in such a way that it would not absorb heat" or whether "a defect in the materials used resulted in the absorption of heat." *Id.*

Here, Plaintiffs allege that the Recalled Devices were defective in design but weave throughout these allegations pleadings that could support that Respironics also manufactured the Devices in a defective way. In Paragraph 327 of the PIAC, Plaintiffs specifically allege the Recalled devices are "defective in design." PIAC (ECF No. 834) at ¶ 327. However, Plaintiffs go on to allege that "Philips had designed, developed, and manufactured the subject devices in a way as to make the risk of harm or injury outweigh any benefits." *Id.* at ¶ 332. Plaintiffs further allege that Philips ". . . *manufactured* . . . the defective Recalled Devices" and "expected the Recalled Devices to reach Plaintiffs "without substantial change in the condition in which the Recalled Devices were *manufactured*, sold, distributed, and marketed by Philips and PolyTech." *Id.* at ¶ 337, 335 (emphasis added). Thus, Plaintiffs have demonstrated there may also be a possibility that discovery will reveal information

demonstrating that the devices suffered from a manufacturing defect, rather than a design defect.

Absent additional factual discovery, it would be impossible to determine, on the briefing alone, what type of defect allegedly manifested in the Devices and when that manifestation would have occurred. Without information as to the type of defect and the manifestation of the defect, it cannot be determined whether the defect manifested within the two-year warranty the Recalled Devices provided. Because a determination of the timeliness of Plaintiffs' claims depends upon a determination of the defect at issue, it will be recommended a determination on this issue should be deferred until completion of discovery.

Similarly, whether the duration of the limited warranty is unconscionable cannot be made at this stage of the case. Such a determination should be made only once it is determined whether the warranty is applicable to the alleged defects, following discovery. Similarly, determinations of whether Plaintiffs were entitled to warranty relief and whether Respironics failed to provide that warranty relief also depend upon a determination of the type of defect present and whether the warranty encompassed that type of defect. Accordingly, it will be recommended that the Court deny Respironics's motion to dismiss Plaintiffs' warranty claims for timeliness. Respironics may reassert these arguments on a full factual record following discovery.

2. Implied Warranty Claims Arising under Pennsylvania Law

Respironics asserts Pennsylvania law bars claims for breach of implied warranties for prescription medical devices and thus, Plaintiffs' claims for breach of implied warranty arising under Pennsylvania law must be dismissed. *See* Supp. Br. (ECF No. 1346) at 36. Contending that the Pennsylvania Supreme Court has not clearly addressed this question and, relying on *Stevens v. C.R. Bard, Inc*., No. 17-cv-1388, 2018 WL 692097 at *8 (W.D. Pa. Feb. 2, 2018), Plaintiffs assert that this court should " 'not dismiss these claims solely upon a prognostic basis.'" Opp. Br. (ECF No. 1644) at 37.

In *Makripodis by Makripodis v. Merrell-Dow Pharmaceuticals, Inc.*, the court noted the risks associated with allowing claims for breaches of implied warranty for prescription items, holding that "the very nature of prescription drugs" precludes imposition of breach of implied warranty because it is impossible to warrant prescription drugs' safety to all users when all users have unique medical histories. 523 A.2d 374, 377 (Pa. Super. Ct. 1986). Thus, Respironics correctly asserts Pennsylvania law looks unfavorably upon breach of implied warranty claims arising from prescription drug use.

Indeed, courts interpreting *Makripodis* have held that these holdings "preclude a claim against a prescription drug manufacturer based on an alleged breach of warranty." *Bell v. Boehringer Ingelheim Pharmaceuticals, Inc*., No. 17-

1153, 2018 WL 928237 at *3 (W.D. Pa. Feb. 15, 2018) (Conti, J.); *see also Killen v. Stryker Spine*, No. 11-1508, 2012 WL 4498865 at *4 (W.D. Pa. Sept. 28, 2012) (holding implied warranty claim based on design defect "is not cognizable under Pennsylvania law and must be dismissed.") (Conti, J.); *Kline v. Zimmer Holdings, Inc*., No. 13-513, 2013 WL 3279797 at *6-7 (W.D. Pa. June 27, 2013) (relying on *Dougherty* and *Kline* to dismiss plaintiffs' claim for breach of implied warranty of merchantability based upon design defect); *Terrell v. Davol, Inc*., No. 13-5074, 2014 WL 3746532 at *7 (E.D. Pa. July 30. 2014) (dismissing claim for breach of implied warranty for medical device arising under Pennsylvania law); *Aaron v. Wyeth*, No. 2:07-cv-927, 2010 WL 653984 at *11 (W.D. Pa. Feb. 19, 2010) (dismissing breach of warranty claim against drug manufacturer).

District courts have predicted that claims for breach of implied warranties arising from design defects in a prescription medical device would likewise be barred under Pennsylvania law. *Dougherty v. C.R. Bard, Inc*., No. 11-6048, 2012 WL 2940727 at *7 (E.D. Pa. July 18, 2012) (holding implied warranty claims based on a design defect or a failure to warn are not cognizable under Pennsylvania law). Specifically in *Dougherty*, Judge Yohn recognized the inconsistency in allowing breach of implied warranty claims against a prescription device manufacturer to continue, noting it would be "inconsistent to exempt a manufacturer of prescription medical devices from strict liability under [Restatement] comment k and apply a

negligence standard to determine liability for a design defect or a failure to warn, but allow a plaintiff to recover for the same alleged defect under a theory of breach of the implied warranty of merchantability." *Id.*

The prescription nature of the devices and the nature of breach of implied warranty claims implies that these opinions are equally persuasive here as they would be if the products at issue were prescription drugs. Accordingly, it will be recommended that the Court grant Respironics's motion to dismiss the breach of implied warranty claims for prescription medical devices under Pennsylvania law.

3. Privity

Respironics asserts that Plaintiffs' implied warranty claims fail for a lack of privity in seven jurisdictions. Supp. Br. (ECF No. 1346) at 35. Specifically, Respironics argues that the laws of Arizona, Florida, Georgia, Idaho, Kentucky, Oregon, and Wisconsin effectively insulate it from liability because they require privity to state a breach of warranty claim. *Id.* The law of each of these states will be considered in turn.

i. Arizona

In *Chaurasia v. General Motors Corp.* 126 P.3d 165, 172 (Ariz. 2006), the Arizona Court of Appeals ruled that "[n]o privity is required for certain personally injured plaintiffs to sue" for breach of implied warranty. Although the issue is far from clear, the pronouncement in *Chaurasia* affords a sufficient reason to

recommend that the Court deny Respironics's motion to dismiss Plaintiffs' implied warranty claims.

ii. Florida

The Florida Court of Appeals has generally acknowledged that "[p]rivity is required in order to recover damages from the seller of a product for breach of express or implied warranties." *Intergraph Corp. v. Stearman*, 555 So.2d 1282, 1283 (Fla. Dist. Ct. App. 1990). District courts interpreting this standard and applying it to medical devices, like the Recalled Devices here, have held that a plaintiff must demonstrate privity to recover for personal injuries caused by a breach of an implied warranty. *Cruz v. Mylan, Inc*., 2010 WL 598688 at *2 (M.D. Fl. Feb. 17, 2010) (granting defendant's motion to dismiss for lack of privity where decedent who overdosed on fentanyl drug was not in privity with manufacturer by virtue of the prescription nature of the drug); *Douse v. Boston Scientific Corporation*, 314 F.Supp.3d 1251, 1262 (M.D. Fl. 2018) (granting motion to dismiss because plaintiffs' physician's reliance on brochures produced by manufacturer was insufficient to establish privity); *Kirchman v. Novartis Pharmaceuticals Corp*., No. 8:06-cv-1787-T-24-TBM, 2014 WL 2158519 at *6 (M.D. Fl. May 23, 2014) (granting motion for summary judgment for breach of implied warranty claims where plaintiff provided no evidence he purchased drugs from manufacturer, and thus lacked privity). Where a plaintiff does not choose the device, but rather, the

plaintiff's physician chooses a device, courts interpreting Florida law have recognized this is insufficient evidence to demonstrate privity. *Pritchett v. Argon Medical Devices, Inc*., No. 6:21-cv-1400-PGB-GJK, 2022 WL 19914513 at *4 (M.D. Fla. Jan. 13, 2022) (granting motion to dismiss breach of implied warranty claim for lack of privity where plaintiffs' physicians chose and purchased implantable medical device for plaintiff).

Here, Plaintiffs have not alleged that they purchased the Recalled Devices from Respironics. Rather, Plaintiffs generally allege they "paid for, purchased, leased, or otherwise acquired a Recalled Device" without alleging they purchased them directly from Respironics. *See* PIAC (ECF No. 834) at ¶ 25. Moreover, at oral argument regarding whether the Recalled Devices are consumer products, Plaintiffs' counsel asserted that Plaintiffs would purchase the devices from a durable medical equipment provider after receiving a prescription, rather than purchasing them directly from Respironics. Or. Arg. J. 10 (ECF No. 2129) 160:9-13, 176:7-13. Thus, Plaintiffs have presented no evidence they can establish they entered into a contractual relationship with Respironics via the purchase of a Recalled Device.

In light of the clarity of Florida law requiring privity for breaches of implied warranties in this context, it will be recommended that the Court grant Respironics's motion to dismiss Plaintiffs' breach of implied warranty claims arising under Florida law.

iii. Georgia

Although certain cases can be read to require direct vertical privity to bring a claim for breach of implied warranty under Georgia law, the Georgia Supreme Court has recognized a broad exception to this privity requirement which is applicable here. In *Jones v. Cranman's Sporting Goods*, the Georgia Supreme Court ruled that a manufacturer who "fully guaranteed" a product to the ultimate consumer can be liable to the ultimate consumer of the product, rather than just the direct buyer, for breach of express and implied warranties. 237 S.E.2d 402, 406 (Ga. Ct. App. 1977) (holding document that accompanied rifle warranting that rifle was "fully guaranteed" was representation directed towards ultimate user). For this exception to apply, the representation by the manufacturer to the ultimate consumer must form the basis of the bargain. *Id.*; *American Coach Lines of Orlando, Inc. v. North America Bus Industries, Inc.*, No. 6:09-cv-1999-Orl-19GJK, 2011 WL 653524 at *18 (M.D. Fla. Feb. 14, 2011) (interpreting *Jones*).

Federal courts applying Georgia law have applied this exception in contexts similar to the one presented here. *See Lee v. Mylan, Inc.,* 806 F.Supp.2d 1320, 1326 (M.D. Ga. 2011) (denying motion to dismiss where drug manufacturer "made affirmations of fact or promises regarding the safety" of the product). This exception also applies to medical devices where a manufacturer expressly warrants the device's functionality in a warranty provided to a patient after selection of the implantable

device. *Cooksey v. Medtronic, Inc*., No. 1:20-CV-00805-ELR, 2021 WL 2481894 at *4-5 (N.D. Ga. June 1, 2021). Even where plaintiffs do not clearly demonstrate, but sufficiently allege, that a representation about the product was made, district courts have allowed a claim to continue. *In re 3M Combat Arms Earplug Products Liability Litigation*, No. 3:19md2885, 2021 WL 753563 at *6 (N.D. Fla. Feb. 2, 2021) (allowing breach of warranty claim to continue absent evidence of privity where plaintiff testified to seeing a flier indicating the product was safe and useful).

Here, the warranty provided in the User Manual is directed towards the end user, rather than the intermediary purchaser. PIAC (ECF No. 834) Ex. 47 at 29. Specifically, the warranty leaves open the identity of the ultimate user and directs its text to the reader of the warranty. *Id.* ("This warranty gives *you* specific legal rights, and *you* may also have other rights that vary from state to state.") (emphasis added). Thus, the warranty operates similarly to the document in *Jones* and this exception to the privity requirement allows Plaintiffs' claims.

At most, pending discovery, this exception should allow Plaintiffs to proceed on their breach of implied warranty claims arising under Georgia law absent privity. Accordingly, it will be recommended that the Court deny Respironics's motion to dismiss the implied warranty claim asserted under Georgia law.

iv. Idaho

Courts interpreting Idaho law regarding the privity requirement for claims of breach of implied warranties have recognized that whether privity is required for such claims depends upon whether the claims are asserted in accordance with the UCC or the Idaho Products Liability Act. *Oats v. Nissan Motor Corp.*, 879 P.2d 1095, 1105 (Idaho 1994) ("[W]hen a plaintiff brings a non-privity breach of warranty action against a manufacturer or seller to recover for personal injuries allegedly sustained as a result of a defective product, that action is one for strict liability in tort, governed by the provisions of the IPLRA."). In the PIAC, Plaintiffs allege a claim for breach of implied warranty of merchantability under Idaho's codified version of the UCC. *See* PIAC, ¶ 513, 537; Idaho Code Ann. § 28-2-318. Accordingly, it will be recommended that the breach of implied warranty claim under Idaho law be dismissed for lack of privity. *See Wilson v. Amneal Pharms., LLC*, No. 1:13-cv-00333, 2013 WL 6909930, at *16 (D. Idaho Dec. 31, 2013) (citing *Oats* to dismiss breach of warranty claim for prescription drug due to lack of privity); *Elliott v. Smith & Nephew, Inc.*, No. 1:12-cv-0070—EJL-MHW, 2013 WL 1622659, at *9 (D. Idaho Apr. 15, 2013) (dismissing claim for breach of implied warranty of medical device because "Idaho does not recognize a breach of warranty claim in personal injury products liability actions which do not involve a contractual relationship between the manufacturer and the injured person."); *Corbett v.*

Remington Arms Company, LLC, No. 4:15-cv-00279-BLW, 2016 WL 1755456 at *2 (D. Idaho May 2, 2016) (dismissing implied warranty claim with prejudice where plaintiff failed to show discovery would demonstrate evidence of privity).

v. Kentucky

Kentucky has codified a privity requirement for claims of breach of implied warranties in Kentucky Revised Statutes Section 355.2-314(1). *See* Ky. Rev. Stat. Ann. § 355.2-314 ("Unless excluded or modified, a warranty that the goods shall be merchantable is implied in a contract for their sale if the seller is a merchant with respect to goods of that kind."). The Kentucky Supreme Court has strictly required privity of contract for breach of implied warranty claims. *See Complex Int'l Co., Ltd. v. Taylor*, 209 S.W.3d 462, 465 (Ky. 2006) (noting that Kentucky "legislature expressly established the privity requirement."); *see also Hurst v. Dixie Truss, Inc*., No. 2020-CA-0816-MR, 2021 WL 1826881 at *4 (Ky. Ct. App. May 7, 2021) (applying *Complex Int'l Co., Ltd*. to deny implied breach of warranty claim for personal injuries for lack of privity); *Jones by and through Jones v. IC Bus, LLC*, 626 S.W.3d 661, 685 (Ky. Ct. App. 2020) (applying *Complex Int'l Co., Ltd*. to dismiss breach of implied warranty claim for lack of privity). Accordingly, it will be recommended that Respironics's motion to dismiss the breach of implied warranty claim under Kentucky law be granted. *See Simpson v. Champion Petfoods, USA, Inc*., 397 F.Supp.3d 952, 969 (E.D. Ky. 2019) (dismissing breach of implied

warranty claim for lack of privity at motion to dismiss stage); *Bosch v. Bayer Healthcare Pharmaceuticals, Inc.,* 13 F.Supp.3d 730, 749 (W.D. Ky. 2014) (granting motion to dismiss claim for personal injuries arising from prescription device for lack of privity where Complaint "shows that Plaintiffs and [manufacturer] are not, and cannot be, in a buyer seller relationship" where plaintiffs obtained device from medical service provider, not from manufacturer); *Sims v. Atrium Medical Corp*., 349 F.Supp.3d 628, 642 (W.D. Ky. 2018) (dismissing breach of implied warranty claim for lack of privity in claim for personal injuries arising from medical mesh).

vi. Oregon

Federal courts assessing breach of implied warranty claims for recovery of personal injuries have been hesitant to dismiss a plaintiff's claim for lack of privity because Oregon courts have not clearly held that a lack of privity bars a claim for breach of implied warranties. *See Smith v. Ethicon, Inc*., No. 3:20-cv-00851-AC, 2021 WL 3578681 at *8 (D. Or. May 13, 2021) (declining to dismiss implied warranty claim of direct purchaser in absence of clear Oregon case law on point); *Allen v. G.D. Searle & Co*., 708 F. Supp. 1142, 1160 (D. Or. 1989) (noting Oregon breach of implied warranty decisions "have carefully distinguished claims for personal injuries by remote purchasers of consumer goods" but allowing claim "in the of absence of a case on point.") In light of this lack of clarity and considering "'[t]he fact-intensive nature of privity frequently renders dismissal at the pleading

stage premature,'" *Rieger v. Volkswagen Group of America, Inc*., No. 1:21-cv-10546—NLH-EAP, 2023 WL 3271116 at *13 (D.N.J. 2023), it will be recommended that the Court deny Respironics's motion to dismiss Plaintiffs' breach of implied warranty claims arising under Oregon law.

vii. Wisconsin

Federal courts applying Wisconsin law have repeatedly recognized that an individual cannot recover for personal injuries absent privity. *Staudt v. Artifex, Ltd.,* 16 F. Supp. 2d 1023, 1030 (E.D. Wis. 1998); *Berres v. Artifex, Ltd*., 21 F.Supp.2d 909, 916 (E.D. Wis. 1998) (dismissing implied warranty claims for lack of privity of contract); *Dippel v. Sciano*, 155 N.W.2d 55, 59-60 (Wis. 1967). *Staudt* and *Berres* present a similar case to the one presented here. There, both plaintiffs sought to recover for a breach of implied warranty associated with defective bone screws produced by manufacturer defendant Artifex. *Staudt*, 16 F.Supp.2d at 1023; *Berres*, 21 F.Supp.2d at 911. Applying the opinion of the Wisconsin Supreme Court in *City of La Crosse v. Schubert, Schroeder & Associates, Inc*., 240 N.W.2d 124 (Wis. 1976) rev'd on other grounds by *Daanen & Janssen, Inc. v. Cedarrapids, Inc*., 573 N.W.2d 842 (1998), the courts dismissed plaintiffs' implied warranty claims for lack of privity. *Staudt*, 16 F.Supp.2d at 1030; *Berres*, 21 F.Supp.2d at 916. Accordingly, it

will be recommended that the Court grant Respironics's motion to dismiss the implied warranty claims of asserted under Wisconsin law.

G. Pre-Suit Notice

Respironics alleges that Plaintiffs' express and implied warranty claims and consumer protection law claims should be dismissed for failure to provide the required pre-suit notice. Supp. Br. (ECF No. 1346) at 36. For the reasons set forth on the pre-suit notice issue raised with respect to the state consumer protection law, it will be recommended that the Court deny Respironics's motion to dismiss warranty claims based upon the lack of pre-suit notice. See Section B, *infra.*

H. Negligent Manufacturing

Plaintiffs allege that Defendants had a duty to design, manufacture, formulate, test, package, label, make, construct, assemble, among other things, the Devices with reasonable and due care. PIAC (ECF No. 834) at ¶ 471. They claim that the Devices reached Plaintiffs, foreseeable users of the Devices, without substantial changes. *Id.* at ¶¶ 472-74, 479. The manufacturing of the Devices was allegedly defective because the PE-PUR foam emitted toxic and carcinogenic chemicals and particles causing a plethora of deleterious health conditions. *Id.* at ¶ 475. Thus, Plaintiffs assert the way the Devices were manufactured was unsafe and unreasonably dangerous. *Id.* at ¶¶ 477-78.

Respironics contends that Plaintiffs' negligent manufacturing claim amounts to a negligent design claim in disguise because it alleges no negligence during the manufacturing process, but rather the design process. Supp. Br. (ECF No. 1346) at 41. Without any factual allegations regarding what went wrong during the manufacturing process, it is not a viable claim. *Id.* According to Respironics, the selection of an improper component is a failure of design. Repl. Br. (ECF No. 1827) at 26. In the absence of an allegation that a different mode or process of manufacturing would result in a properly functioning device, there is not a valid negligent manufacturing claim. *Id.*

Plaintiffs allege that the complaint is filled with facts regarding how the manufacture of the Devices fell below reasonable standards. Opp. Br. (ECF No. 1644) at 41-42 (citing PIAC (ECF No. 834) at ¶¶ 125, 192, 312, 468-85). Moreover, argue Plaintiffs, this issue is better decided after discovery. *Id.* at 42.

To successfully state a claim for negligent manufacturing, Plaintiffs must, "allege some facts that would plausibly suggest that the manufacturer failed to exercise a reasonable standard of care during the manufacturing process." *Foge, McKeever LLC v. Zoetis Inc.*, 565 F.Supp.3d 647, 654 (W.D. Pa. 2021); *see also Smith v. Howmedica Osteonics Corp.*, 251 F.Supp.3d 844, 853 (E.D. Pa. 2017); *Zetz v. Bos. Sci. Corp.*, 398 F.Supp.3d 700, 708-09 (E.D. Cal. 2019) (holding that an implanted product degrading and fragmenting did not constitute a manufacturing

defect because the pleadings failed to identify or explain how the defect related to the manufacture). Plaintiffs' allegations must specify that something went wrong during the manufacturing process. *Id.*

In *McGrain v. C.R. Bard, Inc*., the court determined that a plaintiff's complaint which alleged merely that the defendant "failed to exercise reasonable care" in manufacturing a given product or that the product was "unreasonably dangerous" when manufactured was insufficient to survive a motion to dismiss. 551 F.Supp.3d 529, 540-41 (E.D. Pa. 2021). The Court in *McGrain* stated that for a plaintiff to survive a motion to dismiss they must state a "factual allegation as to the nature of what went wrong *during* the manufacturing process." *Id*. (emphasis added); *See also Mikula v. C.R. Bard, Inc.*, No. 2:21-CV-01307-MJH, 2021 WL 5989130, *3 (W.D. Pa. Dec. 17, 2021) (absent any factual allegation as to the nature of any deficiencies in the manufacturing process, a plaintiff cannot state a claim for negligent manufacture). *Cummings v. FCA US LLC*, 401 F.Supp.3d 288 (N.D.N.Y. 2019) (holding that where a plaintiff makes limited conclusory references to a defect in manufacturing, unsupported by factual allegations, and ultimately more suggestive of a design defect, the claim is insufficient).

Here, several allegations relate to Plaintiffs' negligent manufacturing claim. *See e.g.* PIAC (ECF No. 834) at ¶ 125 (stating that the FDA determined that the Devices failed to comply with federally-mandated "Good Manufacturing Practice

requirements ("GMPs)); PIAC (ECF No. 834) at ¶ 192 (stating that the FDA found that there are reasonable grounds to believe that the Devices were not properly manufactured); PIAC (ECF No. 834) at ¶ 312 (stating Respironics knew or should have known that the Devices did not comply with best manufacturing practices and regulations). The PIAC alleges that "the FDA determined that Philips' manufacture of the Recalled Devices failed to comply with the GMPs imposed by FDA's 'Quality System Regulation' ('QSR') "since at least November 2015." *Id.* at ¶ 126. These averments are enough to support Plaintiffs' claim for negligent manufacturing. Accordingly, it will be recommended that Respironics's motion to dismiss Plaintiffs' negligent manufacturing claim be denied.

I. Strict Liability Design Defect

Plaintiffs allege that Respironics and Polytech were involved in the design, development, manufacture, sale, and distribution of the Devices. PIAC (ECF No. 834) at ¶¶ 325, 337. Plaintiffs, foreseeable users of the Devices, in fact used the Devices in the intended manner. *Id.* at ¶¶ 326, 329. The Devices were defective in design because the PE-PUR foam making up part of the Devices is subject to degradation into toxic and carcinogenic materials which were inhaled and ingested by Plaintiffs. *Id.* at ¶ 327. The chemicals are known to cause cancer, COPD, cardiac injuries, respiratory issues, among other listed deleterious health effects. *Id.* The unreasonably dangerous Devices were unsafe because of the design defect. *Id.* at ¶¶

329-30. According to Plaintiffs, the Devices were unreasonable dangerous, unsafe, and defective when they left Defendants' possession and were not substantially changed when they left Defendants' possession. *Id.* at ¶¶ 331, 335. Plaintiffs also allege that Plaintiffs could not discover the defect through reasonable diligence and safer alternatives were available without the PE-PUR foam with other sound abatement technologies. *Id.* at ¶¶ 332-33.

Respironics first argues that three states do not allow for product liability claims based on strict liability – encompassing both manufacturing *and* design defect.[20] Supp. Br. (ECF No. 1346) at 37. Respironics then argues that under the laws of fourteen states and the District of Columbia, Plaintiffs' claims are barred because those jurisdictions have adopted comment k of the Restatement (Second) of Torts.[21] *Id*. Under comment k, manufacturers of unavoidably unsafe products are not liable for injuries under strict liability defective design. *Id.* According to Respironics, those jurisdictions have found that prescription medical devices are unavoidably unsafe. *Id.* at 37-38.

Respironics represents that in Pennsylvania, comment k bars strict liability design defect claims regarding all medical devices and prescription drugs. *Id.* at 38.

[20] Naming Delaware, North Carolina, and Virginia.
[21] Naming California, District of Columbia, Indiana, Iowa, Maryland, Massachusetts, Montana, New Mexico, New York, Ohio, Pennsylvania, South Dakota, Tennessee, Texas, and Wyoming.

However, they also acknowledge that some district courts have declined to extend comment k to prescription medical devices. *Id.* at 39. They argue that without Third Circuit or Supreme Court precedent, this Court must defer to the one existing intermediate appellate decision and hold that comment k applies to medical device manufacturers. *Id.* at 39-40.

Plaintiffs respond that most states that Respironics cites apply comment k on a case-by-case basis because it is an issue of fact rather than simply a matter of law. Opp. Br. (ECF No. 1644) at 38. Moreover, some states limit it to injuries caused by prescription medicine or implanted medical products. *Id.* Some states do not extend it to medical devices at all. *Id.* Plaintiffs further argue that Respironics minimizes recent development in Pennsylvania law. *Id.* at 39. Per Plaintiffs, there is little evidence to support a prediction that the Pennsylvania Supreme Court would expand comment k to medical devices as categorically exempt from strict liability. *Id.* at 39-40.

Under Delaware, North Carolina, and Virginia law, product liability claims based on strict liability manufacturing and design defects are barred. *See Cline v. Prowler Indus. of Maryland, Inc.,* 418 A.2d 968, 980 (Del. 1980); *Stoddard v. Wyeth, Inc.,* 630 F.Supp.2d 631, 632 (E.D.N.C. 2009); *Harris v. TI, Inc.,* 413 S.E.2d 605, 609-10 (Va. 1992). Therefore, it will be recommended that Respironics's motion to

dismiss the strict liability design and manufacturing defect claims in Delaware, North Carolina, and Virginia be granted.

Manufacturers of "unavoidably unsafe"" products are not liable for injuries under a strict liability defective design theory for states that have adopted comment k to the Restatement (Second) of Torts § 402A. Comment k states:

> There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. . . . The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.

California courts extend comment k to *implanted* prescription medical devices – and thus companies cannot be held strictly held liable for design defects related to those products. *Yalter v. Endocare*, Inc., No. SAC03 80 DOC, 2004 WL 5237598, at *5 (C.D. Cal. Nov. 8, 2004). It is not clear that the California Supreme Court would apply comment *k* to a prescription medical device of the type at issue here.

The District of Columbia limits its application of comment k to prescription drugs. *Dyson v. Winfield*, 113 F.Supp.2d 35, 39-40 (D.D.C. 2000), *aff'd sub nom. Dyson v. Pharmacia & Upjohn Co.*, 21 F. App'x 2 (D.C. Cir. 2001). Accordingly, it will be recommended that the Court deny Respironics's motion to

dismiss the strict liability claims asserted under the District of Columbia and California law.

In Indiana, comment k applies to prescription medical devices as well as prescription drugs. *Parks v. Danek Med., Inc.*, No. 2:95 CV 206, 1999 WL 1129706, *6 (N.D. Ind. June 17, 1999). Thus, strict liability claims for design defects in medical devices are barred. *See id.* Moreover, comment k has been codified in Indiana law, and does not limit its application to drugs or implanted medical devices: "a product is not defective under this article if the product is incapable of being made safe for its reasonably expectable use, when manufactured, sold, handled, and packaged properly." Ind. Code Ann. § 34-20-4-4. Accordingly, it will be recommended that the Court grant the motion to dismiss the strict liability claim under Indiana law.

Iowa law is not clear as to what products are subject to comment k. *Moore v. Vanderloo*, 386 N.W.2d 108, 116 (Iowa 1986) (stating that R2d § 402A., cmt *k*. may be applied to bar strict liability when adequate warning accompanies the product in question); *Petty v. United States,* 740 F.2d 1428, 1439 (8th Cir. 1984) (acknowledging that Iowa would adopt R2d § 402A., cmt *k*., but holding in the matter at issue that the duty to adequately warn was not met and, thus, imposing strict liability). It will be recommended that the Court deny Respironics's motion to dismiss the strict liability design defect claim asserted under Iowa law at this time.

Maryland has adopted comment k, but it does not apply undiscerningly to all drugs and medical devices. *Conway v. Am. Med. Sys., Inc.*, No. CV GLR-18-1466, 2021 WL 6126293, *8 (D. Md. Dec. 28, 2021) (explaining in footnote thirteen that the Maryland Court of Appeals has adopted comment k and excluded some unavoidably unsafe products from strict liability after "weighing the risks of the product against its usefulness under several factors"); *See also Doe v. Miles Lab'ys, Inc., Cutter Lab'ys Div.*, 927 F.2d 187, 191 (4th Cir. 1991) (listing the four elements which must be satisfied to invoke comment k). Here, the parties have not provided any argument regarding those four factors or elements. Therefore, it will be recommended that the Court deny Respironics's motion to dismiss the strict liability design defect claim asserted under Maryland law at this time.

Massachusetts employs a product-by-product analysis to determine whether a medical device is unavoidably unsafe pursuant to comment k and therefore not subject to strict products liability claims. *Taupier v. Davol, Inc.*, 490 F.Supp.3d 430, 443 (D. Mass. 2020); *Lareau v. Page*, 840 F. Supp. 920 (D. Mass. 1993), *aff'd*, 39 F.3d 384 (1st Cir. 1994) (stating that in Massachusetts, "a product liability breach of warranty claim is the functional equivalent of the cause of action upon strict liability"). Therefore, similar to Maryland and considering the deferential standard applied to a motion to dismiss, it will be recommended that the Court deny Respironics's motion to dismiss the strict liability claim under Massachusetts law.

Montana has adopted comment k for unavoidably unsafe products where they are accompanied by proper directions and warnings. *Davis v. Wyeth Lab'ys, Inc.*, 399 F.2d 121, 128-29 (9th Cir. 1968). Montana, however, has not applied comment k to medical devices and at least one federal court has declined to do so. *Dalbotten v. C. R. Bard, Inc.*, No. 1:20-CV-00034-SPW, 2023 WL 157735, *5 (D. Mont. Jan. 11, 2023). Accordingly, it will be recommended that the Court deny Respironics's motion to dismiss the strict liability claim under Montana law.

In New Mexico, comment k has been held to apply to medical devices where, even in the absence of defective design or manufacture, the device had a known risk and was not guaranteed for long term results. *Perfetti v. McGhan Medical*, 662 P.2d 646, 649–50 (N.M. Ct. App. 1983). Here, Respironics has not claimed that their product had "no alternative design." *See Rimbert v. Eli Lilly & Co.*, 577 F.Supp.2d 1174, 1236 (D.N.M. 2008). Moreover, in consideration of the required case-by-case analysis and reading the pleadings and arguments in the light most favorable to Plaintiffs, alternatively designed CPAP Machines do not have the same inherent risks as those designed and manufactured by Respironics. *See McDonald v. Zimmer Inc.*, 461 P.3d 930, 944-45 (N.M. Ct. App. 2019). Accordingly, it will be recommended that the Court deny Respironics's motion to dismiss the strict liability claim under New Mexico law.

New York does not categorically apply comment k to all medical devices. *Arruda v. C.R. Bard, Inc.*, No. 619CV1523TJMATB,, *5-6 (N.D.N.Y. Aug. 6, 2020) (pointing out that no New York court has held all medical devices to be unavoidably unsafe, and courts may apply a utility/risk analysis rather than the unavoidably unsafe exception); *See also Williamson v. Stryker Corp.*, No. 12 CIV. 7083 CM, 2013 WL 3833081 (S.D.N.Y. July 23, 2013) (stating that the Second Circuit assesses "the viability of the design defect claim under the legal standard for such claims in New York – the 'utility/risk analysis'—rather than by applying the unavoidably unsafe products exception"). The court in *Arruda* also found that where a device was not prescribed in a life-or-death scenario, was not experimental, did not have unavoidable adverse consequences, and in fact may have exacerbated a patient's condition, that device was not unavoidably unsafe under comment k and a strict liability design defect claim was permitted. *Id.* at 6. Accordingly, it will be recommended that the Court deny Respironics's motion to dismiss the strict liability claim under New York law.

Ohio has codified comment k and determined that "unavoidably unsafe" means that, "in the state of technical, scientific, and medical knowledge at the time a product in question left the control of its manufacturer, an aspect of that product was incapable of being made safe." Ohio Rev. Code Ann. § 2307.71(A)(16). Under that definition, determining whether a device is unavoidably unsafe would require

an assessment of the available medical knowledge and alternative designs. Moreover, the cases that the parties cited seem to favor analysis of the particular device at issue. *Aaron v. Medtronic, Inc.*, 209 F.Supp.3d 994, 1013-14 (S.D. Ohio 2016) (determining that the device at issue was unavoidably unsafe and not subject to a strict liability claim because it was designated a class III restricted device that presented a "potential unreasonable risk of illness or injury" and "potentiality for harmful effect" with no alternate design that could "lawfully be marketed"); *Thompson v. DePuy Orthopaedics, Inc.*, No. 1:13-CV-00602, 2015 WL 7888387, *15 (S.D. Ohio Dec. 4, 2015) (stating that not all prescription medical devices are unavoidably unsafe). Accordingly, it will be recommended that the Court deny Respironics's motion to dismiss the strict liability claim under Ohio law.

In Pennsylvania, the authority weighs in favor of moving on to discovery to determine whether the facts of the case support strict liability based on a design defect. Pennsylvania law has changed over time – Respironics relies on authority that is out of date. *See e.g. Creazzo*, 903 A.2d at 26; *Parkinson v. Guidant Corp*., 315 F.Supp.2d 741, 747 (W.D. Pa. 2004) (stating that "while it is true that no Pennsylvania court expressly has applied comment K to prescription medical devices, numerous courts in the Eastern District of Pennsylvania . . . have predicted that the Pennsylvania Supreme Court will extend comment K to such devices"). In *Creazzo*, the court held that there was "no reason why the same rational [sic]

applicable to prescription drugs may not be applied to medical devices." *Id.* at 31. *See also Davenport v. Medtronic*, Inc., 302 F. Supp. 2d 419, 441-42 (E.D. Pa. 2004); *Murray v. Synthes, U.S.A., Inc.,* No. CIV. A. 95-7796, 1999 WL 672937 (E.D. Pa. Aug. 23, 1999); *Taylor v. Danek Med., Inc*., No. Civ. A. 95-7232, 1998 WL 96202 (E.D. Pa. Dec. 29, 1998).

However, since *Tincher* and *Lance* were decided in 2014 by the Pennsylvania Supreme Court, the District Courts in Pennsylvania have become reluctant to apply a blanket exemption from strict liability for design defect in favor of a manufacturer of a medical device – undermining the persuasive nature of *Creazzo*. *Tincher* stands for the proposition that the Pennsylvania Supreme Court will not categorically exempt medical devices from strict liability pursuant to comment k. *Tincher v. Omega Flex, Inc.,* 104 A.3d 328, 386, 396 (Pa. 2014) (finding for a more fact-specific approach, and holding that strict products liability may be imposed when a plaintiff shows either that that danger is unknowable and unacceptable, or that a reasonable person would conclude that the risk of harm caused by the product outweighs the burden or costs of taking precautions). *Lance* also stands for a determination on a case-by-case basis despite *Lance* being applied solely to prescription drugs. *Lance v. Wyeth*, 85 A.3d 434 (Pa. 2014); *see also Cohen v. Johnson & Johnson*, No. 2:20-cv-00057, 2022 WL 5109167, at *7 (W.D. Pa. Oct. 5, 2022) (stating that "reading *Lance* and *Tincher* together, this Court is persuaded that

comment k likely would not be applied by the Pennsylvania Supreme Court to categorically bar the applicability of strict liability principles as to all medical devices"); *Spear v. Atrium Med. Corp.*, No. 22-876, 2022 WL 3357485, at *1 (E.D. Pa. Aug. 12, 2022) (holding that under Pennsylvania law, there is little to support a prediction that the Supreme Court would expand Comment k to medical devices). Thus, the weight of the authority weighs in favor of moving on to discovery to determine whether the facts of the case support strict liability based on a design defect. Accordingly, it will be recommended that the Court deny Respironics's motion to dismiss the strict liability claim under Pennsylvania law.

South Dakota caselaw is not clear on whether comment k applies categorically to all medical devices. *McElhaney v. Eli Lilly & Co.*, 575 F. Supp. 228, 230-32 (D.S.D. 1983), *aff'd*, 739 F.2d 340 (8th Cir. 1984) (applying comment k to the prescription drug at issue in the absence of evidence that the defendant knew of or should have foreseen the adverse side effects at issue). The absence of conclusive state law on the issue, and the deferential review standard at the motion to dismiss phase favors allowing Plaintiffs' South Dakota claims to go forward.

Under Tennessee law, comment k applies to medical devices where physicians are adequately warned about risks associated with said devices. *Nolen v. C.R. Bard Inc.*, 533 F.Supp.3d 584, 592 (M.D. Tenn. 2021); *See also Rodriguez v. Stryker Corp.*, 680 F.3d 568 (6th Cir. 2012) (applying comment k after the defendant's

failure to warn claim arguments failed). Here, Plaintiffs allege that there was not adequate warning. For that reason, it is recommended that the court deny Respironics's motion to dismiss on the basis of Tennessee law.

Texas has not categorically barred strict liability for prescription medical devices under comment k. *See In re DePuy Orthopaedics, Inc., Pinnacle Hip Implant Prod. Liab. Litig.*, 888 F.3d 753, 772 (5th Cir. 2018) (finding that comment k did not bar the plaintiff's strict liability claims with regard to a medical implant and that Texas caselaw fails to offer guidance on a case-by-case approach to applying comment k). Accordingly, it will be recommended that the Court deny Respironics's motion to dismiss the strict liability claim under Texas law.

In Wyoming, whether comment k applies to bar the application of strict liability to prescription medical devices depends on the adequacy of the directions and warning – a factual question. *Est. of Van Dyke by Van Dyke v. GlaxoSmithKline*, No. 05-CV-153-J, 2006 WL 8430904, *6 (D. Wyo. Nov. 1, 2006). Here, whether the warnings were adequate, or were given at all, is a factual issue. The deferential review standard at the motion to dismiss phase and the fact intensive nature of the adequacy of the warning favor allowing Plaintiffs' Wyoming claims to go forward.

J. Strict Liability Manufacturing Defect

The essence of Respironics's argument is that the manufacturing defect claim solely relates to the Trilogy Evo Ventilator and no other device despite the Trilogy

EVO not being a device listed as a device at issue in this MDL. Supp. Br. (ECF No. 1346) at 40. The initial transfer order only included litigation arising from a voluntary recall of Devices on June 14, 2021. *Id.* (citing ECF No. 203). Respironics argues that dismissal of manufacturing claims concerning the Trilogy Evo Ventilator is required because Plaintiffs cannot add actions to the MDL that were not transferred to the court through the MDL process. *Id.* The transferee court does not have the authority to add actions. Repl. Br. (ECF No. 1827) at 25.

Plaintiffs admit that the Trilogy EVO was not included in the June 14, 2021, recall, but state without contradiction that the FDA subsequently issued a recall of those devices for the same reason as the earlier recall. Opp. Br. (ECF No. 1644) at 40. Precluding the claims, therefore, would unnecessarily cause inefficiencies. *Id.* at 41. Plaintiffs further argue that this court has the authority to determine the scope of the MDL and include devices not originally included. *Id.*

Plaintiffs may not unilaterally add to an MDL . *In re Mortg. Elec. Registration Sys. (Mers) Litig.,* No. MD-09-02119-PHX-JAT, 2016 WL 3931820, *5 (D. Ariz. July 21, 2016). Rather, transfers are made by the Judicial Panel on Multidistrict Litigation. *Id.* After the panel transfers an action to a transferee court, any party can notify the Clerk of the Panel about any "tag-along" actions, and the Clerk may order that action be sent to the transferee court. *Id.* at 6. Plaintiffs' cited cases do not support an alternative mechanism for expanding the scope of an MDL. *See In re*

Exactech Polyethylene Orthopedic Prod. Liab. Litig., No. MDL 3044, 2022 WL 5408779 (U.S. Jud. Pan. Mult. Lit. Oct. 7, 2022). Plaintiffs are thus relegated to the accepted methodology to expand an MDL. It is therefore recommended that Respironics's motion to dismiss Plaintiffs' strict liability manufacturing defect claim with respect to the Trilogy EVO device be granted.

K. Battery

In the Complaint, Plaintiffs allege that all Plaintiffs used a Device, not knowing that these Devices had unwanted, dangerous particles and gasses which were blown into their bodies by the Devices. PIAC (ECF No. 834) at ¶ 436. They further allege that Respironics designed, manufactured, marketed, and sold the Devices with the defects – amounting to an act that caused harmful and offensive touching. *Id.* at ¶ 437. Respironics's actions were allegedly intentional because Respironics had full knowledge that its actions would result in contact that was harmful and offensive and that the ingested chemicals could cause serious health problems. *Id.* at ¶¶ 438-39, 442-43. There was no consent because the chemicals were not ingested knowingly so any purported 'consent' was not "effective." *Id.* at ¶¶440-41.

Respironics argues that a defendant can only be liable for battery if they intended their actions to cause "harmful or offensive contact… or an imminent apprehension of such a contact" and that contact occurs. Supp. Br. (ECF No. 1346) at 50. For there to be intent, the defendant is required to have acted with the purpose

of causing harmful *or* offensive contact or have knowledge that such contact "will, to a substantial certainty, be produced by [the] act." *Id.* Respironics therefore argues that Plaintiffs have not pled intent – Respironics contends that Plaintiffs merely pled that the devices are intended to help people breathe, not that they are meant to be harmful. *Id.* at 51. Regarding the potential knowledge argument, Respironics asserts that Plaintiffs pled no facts that any individual plaintiff was substantially certain to experience harmful contact. *Id.* They argue that allegations of generalized harm are not sufficient. *Id.*

Plaintiffs argue the Complaint alleges that Respironics knew about the defect and the harms Plaintiffs were exposed to and continued selling the device anyway, and that pleading such facts supports a claim for battery. Opp. Br. (ECF No. 1644) at 50. Moreover, there is no need to allege that Respironics had a specific intent to harm Plaintiffs, merely that Respironics intended to take an action that was likely to result in harmful or offensive contact. *Id.* Finally, Plaintiffs argue that the notion that Respironics knew specifically which users would experience the harmful contact is not supported by the law. *Id.*

Section 13 of the Restatement (Second) of Torts provides:

> An actor is subject to liability to another for battery if:
> (a) he acts intending to cause a harmful or offensive contact with the person of the other or a third person, or an imminent apprehension of such a contact, and
> (b) a harmful contact with the person of the other directly or indirectly results.

The Restatement acknowledges that intent does not require the defendant to endeavor to cause the consequences of the act, the defendant must merely have knowledge that the consequences of the act are substantially certain to result. Restatement (Second) of Torts § 8A (1965). *See also Acosta Orellana v. CropLife Int'l*, 711 F. Supp. 2d 81, 90-91 (D.D.C. 2010) (acknowledging that intent can be inferred if the defendant had knowledge that such result would, to substantial certainty, be produced by the act). Intent includes "the desire to bring about the likely consequences of an intentional act." *Field v. Philadelphia Elec. Co.*, 388 Pa. Super. 400, 565 A.2d 1170 (1989).

Courts have held that battery claims are cognizable where a defendant intentionally exposes plaintiffs to harmful chemicals and they know the hazardous nature of those chemicals in the context of how the defendants used them. *Johnson v. Sunoco, Inc. (R&M)*, No. CV 05512, 2018 WL 925009, *4 (E.D. Pa. Feb. 15, 2018) (quoting *Adams v. Dole Food Co.*, 323 P.3d 122, 136 (Ct. App. 2014). In *Johnson*, the defendants supplied solvents containing dangerous chemicals and placed them into the "stream of commerce" knowing and intending individuals to use them. *Id.* at *5. At the time they did so, defendants knew that exposure to such chemicals could lead to blood and bone marrow disorders. *Id.* Under those circumstances, the court found that the plaintiffs stated a claim for battery. *Id.* As explained in Section 18 of the Restatement (Second) of Torts:

> All that is necessary is that the actor intend to cause the other, directly or indirectly, to come in contact with a foreign substance in a manner which the other will reasonably regard as offensive. Thus, if the actor daubs with filth a towel which he expects another to use in wiping his face with the expectation that the other will smear his face with it and the other does so, the actor is liable as fully as though he had directly thrown the filth in the other's face.

Here, Plaintiffs' allegations mirror the hypothetical proffered in the Restatement and *Johnson*. Though they did not know for certain which individual Plaintiffs would experience negative health effects, taking Plaintiffs pleading as true, Respironics knew exposure to the chemicals created by their product could lead to various deleterious medical conditions. Therefore, it is recommended that Respironics's motion to dismiss Plaintiffs' battery claim be denied.

VI. CONCLUSION

For the foregoing reasons, it is hereby recommended that the Court **GRANT** in part and **DENY** in part Respironics's motion to dismiss the PIAC as set forth above. In accordance with Fed. R. Civ. P. 53(f)(2), objections to or requests for modification of this Report and Recommendation must be submitted within twenty-one days.

Dated: September 28, 2023

/s *Thomas I. Vanaskie*
Hon. Thomas I. Vanaskie (Ret.)
Special Master

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

IN RE: PHILIPS RECALLED CPAP, BI-LEVEL PAP, AND VENTILATOR PRODUCTS LITIGATION	Master Docket: Misc. No. 21-
This Document Relates to: All Actions	MDL No. 3014

RECOMMENDATION ON THE MOTION OF DEFENDANT PHILIPS RS NORTH AMERICA LLC TO DISMISS PLAINTIFFS' AMENDED MASTER LONG FORM AND SHORT FORM COMPLAINTS FOR PERSONAL INJURIES AND DAMAGES

For the foregoing reasons provided in the attached Recommendation on the Motion of Defendant Philips RS North America LLC to Dismiss Plaintiffs' Amended Master Long Form and Short Form Complaints for Personal Injuries and Damages, it is recommended that the Court grant the following:

1. Respironics' Motion to Dismiss Plaintiffs' common law claims of negligence, strict liability, express warranty, implied warranty, battery, loss of consortium, wrongful death, medical monitoring, fraud, and consumer protection under the laws of Connecticut, Indiana, Kansas, Louisiana, Mississippi, New Jersey, Ohio, Tennessee, and Washington because such claims are subsumed by the jurisdictions' products liability acts. **(Counts I through XVI, and XVII through XXI)**
2. Respironics' Motion to Dismiss Plaintiffs' claims for negligent recall/negligent failure to recall for the jurisdictions of Alaska, Mississippi, Missouri, Nebraska, Ohio, Pennsylvania, and Texas. **(Count VI)**
3. Respironics' Motion to Dismiss Plaintiffs' negligence per se claims under the laws of California, Hawaii, Louisiana, Maryland, Massachusetts, Michigan, Mississippi, Nevada, North Dakota, Pennsylvania, Texas, Vermont, Virginia, and Washington. **(Count XV).**
4. Respironics's Motion to Dismiss Plaintiffs' common law fraud claims for failure to satisfy Rule 9(b). **(Count XIII).**
5. Respironics's Motion to Dismiss Plaintiffs' negligent misrepresentation claims under the laws of Arkansas, Idaho, Indiana, Maine, North Carolina, and Virginia because these jurisdictions do not recognize an independent

cause of action for negligent misrepresentation or otherwise limit the claim. **(Count XIV).**

6. Respironics's Motion to Dismiss Plaintiffs' negligent misrepresentation claims under the laws of Alabama, Connecticut, New York, and South Dakota for failure to allege a confidential or fiduciary relationship sufficient to establish a duty to disclose in those jurisdictions. **(Count XIV).**
7. Respironics's Motion to Dismiss Plaintiffs' consumer protect law claim **(Count XVI)** under the laws of Alaska, Florida.[22] Hawaii, Iowa, Maine, Nebraska, New Mexico, Ohio, Oregon, Pennsylvania, Tennessee, Texas, and Washington.
8. Respironics's Motion to Dismiss Plaintiffs' claims arising under the laws of Delaware, Georgia, Illinois, Maine, and Nebraska **(Count XVI)** because those jurisdictions' statutes preclude private rights of action for damages.
9. Respironics's Motion to Dismiss Plaintiffs' unjust enrichment claims **(Count XVII)**.
10. Respironics's Motion to Dismiss Plaintiffs' medical monitoring claims under the laws of Montana and New Hampshire. **(Count XX)**.
11. Respironics's Motion to Dismiss Plaintiffs' implied warranty claims under Pennsylvania law. **(Counts XI and XII)**.

[22] It is recommended the Motion be granted only as to Plaintiffs' claims under the FDUTPA.

12. Respironics's Motion to Dismiss Plaintiffs' implied warranty claims under the laws of Florida, Idaho, Kentucky, and Wisconsin **(Counts XI and XII)** for lack of privity.
13. Respironics's Motion to Dismiss Plaintiffs' strict liability design defect claims under the laws of Delaware, North Carolina, and Virginia. **(Counts II, IV, and VII).**
14. Respironics's Motion to Dismiss Plaintiffs' strict liability design defect claims under the laws of Indiana. **(Count II)**.
15. Respironics's Motion to Dismiss Plaintiffs' strict liability manufacturing defect claim **(Count VIII)** with respect to the Trilogy EVO device.

In all other aspects, it is recommended that Respironics Motion to Dismiss be denied.

s/ Thomas I. Vanaskie
Hon. Thomas I. Vanaskie (Ret.)
Special Master

September 28, 2023
Date